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HIGHLIGHTS

LEAD REPORT: High Court's *Stanford* Ruling May Complicate Research
The Supreme Court holds in *Stanford v. Roche* that the Bayh-Dole Act does not bar inventors from assigning their individual rights in patents resulting from federally funded research. Attorneys say that those involved in life sciences-related research in particular must take care to perform due diligence in assessing the research institution's title to the inventions. **Page 403**

Review of Final NIH Conflict-of-Interest Rule Extended by OMB
The White House Office of Management and Budget announces it has extended its review of the National Institutes of Health conflict-of-interest regulations, pushing back the release of a highly anticipated final rule that might tighten federal standards and create more reporting requirements for research institutions. The cause and length of the extension are not clear, but some suggest it may be related to calls for regulatory reform. **Page 407**

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Biomedical research institutions need conflict-of-interest policies for their entire organizations, not just for individuals, Lewis Morris, a deputy inspector general at the Department of Health and Human Services, tells a research compliance conference. Until federal regulations are put in place, he says, research institutions must take the lead in addressing these conflicts by separating financial decisionmaking from research. **Page 433**

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A federal jury in Kansas indicts a doctor and a clinical research coordinator on charges of falsifying study data in a clinical drug trial they were paid to conduct, U.S. Attorney for the District of Kansas Barry Grissom announces. The doctor, Wayne Spencer, and the coordinator, Lisa Sharp, of Lee Research Institute, are charged with conspiracy, mail fraud, and falsifying information required by the Food and Drug Administration in research conducted for Schering-Plough Corp. **Page 427**

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Editor's Note

BNA's *Medical Research Law & Policy Report* is interested in publishing analysis articles by health care practitioners and other experts on subjects of concern to the medical research legal and professional communities, as well as reporting on significant settlements, pending lawsuits, and other developments. If you are interested in writing an article or alerting us to developments that might be of interest, please contact Randy Kubetin, the managing editor, at (703) 341-5715 (e-mail: rkubetin@bna.com), or submit your idea in writing to: Medical Research Law & Policy Report, The Bureau of National Affairs, Inc., 1801 S. Bell St., Arlington, VA 22202.

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Lead Report

Intellectual Property

High Court's *Stanford* Ruling Places Special Demands on Research Entities, Attorneys Say

Attorneys and life sciences companies expressed concern that, as a result of the Supreme Court's June 6 ruling that the Bayh-Dole Act does not bar inventors from assigning their individual rights in patents resulting from federally funded research, a research organization's efforts to properly secure rights to that invention will become more complicated and more demands will be placed on life sciences research than on other areas (*Bd. of Trustees of Leland Stanford Junior University v. Roche Molecular Systems Inc.*, U.S., No. 09-1159, 6/06/11).

In a dispute over patents on HIV technology, the court, in a 7-2 vote, rejected Stanford University's argument that the act automatically vests patent title to universities and other contractors for inventions resulting from research financed at least in part by federal funds.

Carl Gulbrandsen, of the Wisconsin Alumni Research Foundation, in Madison, Wis., was disappointed with the decision. ''It's going to force all the universities to be much more careful in looking at the agreements their faculty are entering,'' he said. He noted that the assignment in the instant case came in a confidentiality agreement, and WARF does not require faculty to disclose such agreements.

Matthew B. McFarlane of Robins, Kaplan, Miller & Ciresi LLP, New York, told BNA that the ''decision clarifies that universities and other research institutions cannot rely solely on the provisions of the Bayh-Dole Act as a universal sword to rescue and secure rights to inventions that may have been supported by funding from the federal government. Like all other employers, these entities need to obtain specific assignment agreements or obligations to assign from their employees and students whose work may result in a future invention.''

The ruling underscores the importance of obtaining effective assignments of inventions made using government funding and also presents practical challenges, Judith Hasko of Latham & Watkins, Menlo Park, Calif., told BNA.

''Research institutions will need to assess whether the assignment clauses in their agreements with researchers will be effective in light of this decision, and if these clauses are not, such institutions will need to alter the language in those agreements to be effective. However, research institutions finding deficiencies in their invention assignment clauses face some practical challenges in changing agreements that they have used for years, and which have been approved by many institutional stakeholders,'' Hasko said.

District Court Sides with Roche, Federal Circuit Reverses. Bayh-Dole—formally the University and Small Business Patent Procedures Act of 1980, 35 U.S.C. §§ 200-212—has a comprehensive set of rules for allocating patent interests among the government, the ''contractor''—generally a university or small business—that the government funded, and the individual inventors listed on the patents.

Just as with any private company, a contractor conducting research funded by the government can eliminate any question of individual researchers' rights to patents arising from the research through appropriate assignment contracts. The instant case arose because Stanford University's employment agreement required researchers to ''agree to assign'' patent rights to the university.

A Stanford employee, Mark Holodniy, on loan to a private research lab that now is part of Roche Molecular Systems, signed a confidentiality agreement that immediately assigned to Roche patent rights in future inventions: ''I will assign and *do hereby assign*'' intellectual property rights.

The patents at issue (5,968,730, 6,503,705, and 7,129,041) involve correlating measurements of HIV nucleic acids to determine whether a particular therapy is effective. Holodniy conceived the procedure while at Roche, then returned to Stanford to conduct clinical studies. Stanford subsequently filed for and was issued the patents. After licensing negotiations with Roche failed, Stanford filed a lawsuit alleging that Roche's HIV detection kits infringed the patents.

The U.S. District Court for the Northern District of California granted Stanford's motion for summary judgment as to whether Roche was an owner of the disputed patents or had a license, thus rejecting Roche's claim that Stanford lacked standing without Holodniy's assignment.

On appeal, the Federal Circuit reversed. The court held that Roche was co-owner of the patents—along with Stanford—because Holodniy had assigned his rights to Roche prior to conception of the invention, 583 F.3d 832 (9 MRLR 44, 1/20/10).

The Supreme Court granted certiorari Nov. 1 (9 MRLR 685, 11/3/10) on the question: ''Whether a federal contractor university's statutory right under the Bayh-Dole Act, 35 U.S.C. §§ 200-212, in inventions arising from federally funded research can be terminated unilaterally by an individual inventor through a separate agreement purporting to assign the inventor's rights to a third party.''

Oral arguments were held Feb. 28, with the U.S. solicitor general participating as amicus curiae in support of Stanford's position. (10 MRLR 149, 3/2/11).

Bayh-Dole Text Dooms Stanford's Arguments. ''Although much in intellectual property law has changed in the 220 years since the first Patent Act, the basic idea that inventors have the right to patent their inventions has not,'' said Chief Justice John G. Roberts Jr., writing for

the majority. ''Only when an invention belongs to the contractor does the Bayh-Dole Act come into play.''

The majority rejected Stanford's argument that this result would fundamentally undermine Bayh-Dole, asserting that current university practice resolves the problem.

Roberts first identified the court's precedents going back to 1851 that ''confirm the general rule that rights in an invention belong to the inventor.''

''It is equally well established that an inventor can assign his rights in an invention to a third party,'' Roberts said, citing *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 188 (U.S. 1933). Also, he asserted, the *Dubilier* court held ''that unless there is an agreement to the contrary, an employer does not have rights in an invention 'which is the original conception of the employee alone.' ''

Rejecting the view of Stanford and the U.S. government that Bayh-Dole trumps those rules, the court distinguished other legislation that specifically vested intellectual property rights in the United States—certain inventions on nuclear materials and atomic energy, in 42 U.S.C. § 2182; pursuant to NASA contracts, in 51 U.S.C. § 20135(b)(1); or funded by the Department of Energy, in 42 U.S.C. § 5908.

''Such language is notably absent from the Bayh-Dole Act,'' the court explained. ''Nowhere in the Act is title expressly vested in contractors or anyone else; nowhere in the Act are inventors expressly deprived of their interest in federally funded inventions.''

The parties contested whether the phrase ''any invention of the contractor'' in the definition of ''subject inventions'' in Section 201(e) of the act, 35 U.S.C. § 201(e), was meant to cover any invention made by the contractor's employees or any invention owned by or belonging to the contractor. The high court agreed with the latter rendering.

You Cannot 'Retain' Unless You Already Have. Another part of the Bayh-Dole text working against Stanford is a provision, Section 202(a), that allows contractors to ''elect to retain title'' to a Bayh-Dole subject invention. ''You cannot retain something unless you already have it,'' the court said. ''The Bayh-Dole Act does not confer title to federally funded inventions on contractors or authorize contractors to unilaterally take title to those inventions; it simply assures contractors that they may keep title to whatever it is they already have.''

Section 210(a) begins, ''This chapter shall take precedence over any other Act which would require a disposition of rights in subject inventions,'' but the court rejected the solicitor general's argument that the phrase overturns the individual inventor's rights. The court noted again that the act applies only to ''subject inventions,'' as it had previously construed that term.

''The Act's disposition of rights—like much of the rest of the Bayh-Dole Act—serves to clarify the order of priority of rights between the Federal Government and a federal contractor in a federally funded invention that already belongs to the contractor,'' Roberts said. ''Nothing more.''

Current Practice Confirms Interpretation. The court then looked at current practice in university employment agreements and found further support.

For example, the court referred to guidance by the National Institutes of Health to contractors, that ''[b]y law, an inventor has initial ownership of an invention'' and that contractors should therefore ''have in place employee agreements requiring an inventor to 'assign' or give ownership of an invention to the organization upon acceptance of Federal funds.''

Thus rejecting Stanford's contention that the court's decision threatens the continued success of Bayh-Dole, the court said, ''With an effective assignment, those inventions—if federally funded—become 'subject inventions' under the Act, and the statute as a practical matter works pretty much the way Stanford says it should. The only significant difference is that it does so without violence to the basic principle of patent law that inventors own their inventions.''

The court thus affirmed the Federal Circuit's decision.

Justices Antonin Scalia, Anthony M. Kennedy, Clarence Thomas, Samuel A. Alito, Sonia Sotomayor, and Elena Kagan joined the opinion.

Dissent Contests Majority's Interpretation of Text. Justice Stephen G. Breyer dissented. He argued that the Federal Circuit's focus on the assignment language in the employment and confidentiality agreements at issue ''seems to make too much of too little.'' He would instead treat both agreements as merely creating equitable rights, and then address the Bayh-Dole questions—not adequately briefed in the case below and so necessitating remand—within that context.

First, Breyer argued that the ability of an individual inventor to assign to a third party inventions resulting from public funding is ''inconsistent with the [Bayh-Dole] Act's basic purposes. It allows individual inventors, for whose invention the public has paid, to avoid the Act's corresponding restrictions and conditions. And it makes the commercialization and marketing of such an invention more difficult.''

Breyer next contended that the text of the Bayh-Dole Act was not so clear cut to support the majority's view. He concluded that the phrase ''invention of the contractor'' must refer its employees' inventions, since a contractor does not conceive of ideas or reduce them to practice ''*other than* through its employees.'' He left as an open question, though, whether ''the term 'subject invention' also include[s] inventions that the employee fails to assign properly.''

Rejecting the majority's reliance on ''background norms of patent law,'' Breyer posited that Bayh-Dole created ''competing norms governing rights in inventions for which the public has already paid, [which] along with the Bayh-Dole Act's objectives, suggest a different result.''

Dissent Contests Federal Circuit's Contracts Rule. Finally, Breyer faulted the Federal Circuit for its rule on assignment language in contracts.

The majority said, in a footnote, ''Because the Federal Circuit's interpretation of the relevant assignment agreements is not an issue on which we granted certiorari, we have no occasion to pass on the validity of the lower court's construction of those agreements.''

However, Breyer addressed squarely the appeals court's analysis that favored the Roche contract. ''Given what seem only slight linguistic differences in the contractual language, this reasoning seems to make too much of too little.'' Citing older treatises on patent law, he contended that ''a present assignment of future inventions (as in both contracts here) conveyed equitable, but not legal title.''

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With both Stanford and Roche thus having only equitable interests in Holodniy's invention, he said, Stanford's prior agreement meant that it should have prevailed.

Breyer thus criticized the Federal Circuit for making ''a significant change in the law'' in *FilmTec Corp. v. Allied-Signal Inc.*, 939 F. 2d 1568 (1991). ''While the cognoscenti may be able to meet the *FilmTec* rule in future contracts simply by copying the precise words blessed by the Federal Circuit, the rule nonetheless remains a technical drafting trap for the unwary.''

He interpreted the majority's footnote as not foreclosing a future challenge to the Federal Circuit's rule, and because it is ''relevant to our efforts to answer the question presented here,'' said that he would vacate the appeals court's judgment and remand the case for more adequate briefing on the issue.

Justice Ruth Bader Ginsburg joined Breyer in dissent. In a one-paragraph concurrence, Justice Sonia Sotomayor also criticized the Federal Circuit's *FilmTec* reasoning, but agreed with the majority because Stanford failed to challenge the decision on those grounds.

Donald B. Ayer, of Jones Day, Washington, represented Stanford. Mark C. Fleming, of Wilmer Hale, Boston, represented Roche. Deputy Solicitor General Malcolm L. Stewart represented the government.

Stanford Disagrees, Others See Pluses, Minuses. Stanford University issued a statement respectfully disagreeing with the decision, citing Justice Breyer's statement in his dissent that the majority's ruling would allow an individual inventor at a university, nonprofit or small business to ''assign an invention (produced by public funds) to a third party, thereby taking that invention out from under the Bayh-Dole Act's restrictions, conditions and allocation rules,'' and that is ''inconsistent with the Act's basic purpose.''

Stanford wrote that it, the federal government, and former Sen. Evan Bayh in his amicus brief had argued that this result was not the intent of Bayh-Dole and has many potential negative consequences for the federal government, which retains certain rights to inventions created with federal funding, for universities and others who create inventions with that funding, and for companies that license the inventions.

''For example, the federal government could lose its many rights in the inventions, could lose the assurance that the royalties that would have gone to the university are used to further scientific research and education, and could lose the requirement that exclusive licensees will manufacture any products substantially in the United States,'' Stanford wrote.

The statement said that while the university was disappointed with the ruling, it will move forward to protect the interests of all parties in inventions created with federal funding, including the interests of the federal government and companies that license technology from Stanford.

''I think the court reached the decision that will cause the least panic,'' Steve S. Chang, of Banner & Witcoff, Washington, told BNA. ''By saying that Bayh-Dole does not automatically transfer ownership, ownership of inventions will be decided under the same terms they have been for many, many years—starting with the inventor, and looking for a chain of assignment agreements. Had the decision gone the other way, it could have raised questions in any assignment that was made by an inventor to someone other than the inventor's employer, something that often happens as companies partner with universities.''

However, William D. Coston, of the Venable law firm, Washington, who wrote a brief on behalf of one of the bill's authors, Bayh, expressed concern. ''The decision could add expense to what is already very expensive patent litigation by having discovery focused on whether all the paperwork is consistent with an inventor's assignment of his or her interest to the university,'' he said.

He faulted the court for ''its explicit focus on the text of the statute'' and for not paying enough attention to the legislative intent of the Bayh-Dole Act. On the other hand, Coston said, ''Going forward, the fundamental purpose of the act remains intact, and it is simply incumbent on universities to make sure their paperwork is in order.''

''From Sen. Bayh's perspective,'' he said, ''while that's an important issue, it's ancillary to the principal beauty of the act, getting inventions in the hands of the universities.''

More Demanding for Life Sciences. The Biotechnology Industry Organization (BIO) issued a joint statement with the Association of American Universities, the American Council on Education, the Association of Public and Land-grant Universities, the Association of University Technology Managers, and the Council on Governmental Relations, noting that the biotechnology industry and the university community rely on effective collaborations to make the products of their research and development available to the public. ''Although BIO and the undersigned higher education associations held different views on the *Stanford v. Roche* case, the organizations are united in the desire to ensure that the U.S. technology transfer system continues to generate these public benefits through the robust provisions of the Bayh-Dole statute. We are committed to working together in light of the Supreme Court's decision to ensure the continued vibrancy of public-private partnerships and success of our shared objectives.''

McFarlane assessed the effect of the ruling on life sciences research. ''In some ways, the task of identifying and securing rights to an invention may be more demanding in life sciences versus other research areas, in part because of the scale of NIH's funding (relative to agencies that fund other disciplines) directed to relatively basic research programs,'' he said. ''At early stages of research and development, an invention may not be clearly identifiable or even capable of sufficient description given the Federal Circuit's en banc restatement of the written description requirement of 35 U.S.C. s. 112, first paragraph in *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*.''

To the extent that progress in the life sciences increasingly depends on the contribution of different individuals and areas of expertise, ''federal funding to any of the research programs contributing to a downstream invention might complicate the analysis of how a research organization should proceed in properly securing rights to that invention,'' McFarlane said.

Hasko stressed the need for those involved in life sciences-related research to take care to perform due diligence in assessing the research institution's title to the inventions.

''For example, they should review the assignment agreements the inventors executed with the research institution, where possible (such agreements may not easily be traced, and may not be made available to the proposed licensee),'' Hasko said. ''Licensees should be aware that even if an invention-specific assignment agreement has been executed by the inventors in a patent filing, if the general assignment clause in the inventor's agreement with the research institution was ineffective, and if the inventor executed an effective assignment clause in an agreement assigning title to the invention to an entity other than the research institution prior to executing the invention-specific assignment to the research institution, it is possible that the invention may not be owned by the research institution.''

Hasko noted that research institutions often provide minimal assurances in license agreements either supporting their title to the funded inventions, or confirming that third parties do not have an ownership interest in such inventions. ''This makes it even more important to perform due diligence inquiries on assignment and title prior to licensing government-funded inventions,'' she said.

BY TONY DUTRA AND JOHN T. AQUINO

The court's opinion is available at http://pub.bna.com/ptcj/091159Jun6.pdf.

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News

Conflict of Interest

Review of Final NIH Conflict-of-Interest Rule Extended by OMB; No Release Date Indicated

The White House Office of Management and Budget announced June 9 it has extended its review of the National Institutes of Health conflict-of-interest regulations, pushing back the release of a highly anticipated final rule that might tighten federal standards and create more reporting requirements for research institutions.

The cause and length of the extension are not clear. NIH referred requests for comment to OMB, which did not return calls before BNA's deadline. OMB received the rule to review March 10 (10 MRLR 191, 3/16/11). While there is no legal deadline to release final rules, the OMB review period typically lasts 90 days, and it had been expected the final rule would be out by late spring or early summer. However, the notice on the website said the proposed changes are in the final rule stage.

NIH seeks to amend the regulations ''Responsibility of Applicants for Promoting Objectivity in Research for Which PHS [Public Health Service] Funding Is Sought'' (42 C.F.R. Part 50, Subpart F). It is the first sweeping set of changes to the rule since 1995 (10 MRLR 191, 3/16/11). The draft changes, released in May 2010, indicate the agency is looking to increase the reporting requirements, lower the monetary thresholds for disclosure to $5,000 from $10,000, and require institutions to post all the disclosures on a publicly accessible website (9 MRLR 335, 6/2/10).

In 2008, the Association of American Universities (AAU) and the Association of American Medical Colleges released a joint set of guidelines on managing conflicts of interest in human subjects research, which offered recommendations for policies on individual and institutional financial conflicts of interest in human subjects research, as well as guidelines for putting those policies into practice (7 MRLR 135, 3/5/08).

Carrie Wolinetz, associate vice president for federal relations at AAU, linked OMB's decision to extend the review of NIH's conflict-of-interest rules to a White House effort to reduce regulatory burdens. Based on a Jan. 18 executive order from President Obama (10 MRLR 75, 2/2/11), OMB announced May 26 a government-wide effort to reduce regulatory burdens, which included plans to enhance research by modifying peer review regulations, streamlining privacy rule requirements, and moving to all-electronic systems of reporting mandatory data (9 MRLR 335, 6/2/11).

''I think it's indicative of the fact that OMB is taking the memorandum and the executive order they issued on regulatory burden very seriously,'' Wolinetz told BNA June 10. ''So I think they're just very closely scrutinizing anything that's coming out that could potentially be burdensome.''

Reporting Requirements Possible Cause. While neither OMB nor NIH has indicated why the review was extended, Carol J. Blum, director of research compliance and administration for the Council on Government Relations, said at a conference in April that her organization and others expressed concern about the public reporting requirements. The effort and money required to develop and maintain these requirements would be greater than NIH had anticipated. However, in a June 13 e-mail to BNA, Blum said she did not know why OMB decided to extend its review of the NIH conflict-of-interest rule and had no comment.

Under the proposed changes, institutions would have to make available via a website interests related to research funded by the Public Health Service and determined to be a potential financial conflict of interest. The requirement would include basic information such as the investigator's name, position, nature of the work, and the value of the financial interest; an annual update; and a posting that lasts for five years.

Wolinetz, who is responsible for NIH and biomedical research issues at AAU, also said the reporting requirements were the biggest concern with respect to burden on the institutions.

''I think that was something the community certainly expressed a concern about being potentially the biggest burden. It wouldn't surprise me if that was the focus of the examination now,'' she said.

When asked about any impact OMB's decision to extend the review will have on the research community, Wolinetz said that while it has been eager to see the final regulations come out, she does not anticipate the delay will affect anyone in the short term.

''A lot of institutions have systems in place at this point, so we'll just continue waiting,'' she said.

BY JEANNIE BAUMANN

The OMB notice is available at http://www.reginfo.gov/public/do/eoPackageMain. Select the option ''Regulations under EO 12866 Review'' and click on ''Department of Health and Human Services'' in the dropdown box.

The proposed changes, ''Amendment of Regulation of the Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought and Responsible Prospective Contractors,'' is available at http://bit.ly/lNVhLf.

Contracts

Sneeze, Wheeze & Itch, Dynavax Settle Clinical Trial Breach-of-Contract Litigation

A federal district court June 2 dismissed breach-of-contract litigation after the plaintiff clinical drug testing facility and the defendant sponsor of clinical drug trials reached a settlement agreement (*Sneeze*

Wheeze & Itch Associates LLC v. Dynavax Technologies Corp., S.D. Ill., No. 1:09-cv-01190-JBM-JAG, *dismissed* 6/2/11).

The agreement was confidential, so its terms were not disclosed.

Sneeze, Wheeze & Itch Associates (SWI), based in Normal, Ill., sued Berkeley, Calif.-based Dynavax Technologies, a sponsor of clinical drug trials, and CRN/Allergy and Respiratory, a network of clinical research sites, in the U.S. District Court for the Southern District of Illinois for breach of contract as a result of nonpayment.

Between Jan. 13, 2003, and July 6, 2007, SWI was a member of CRN/Allergy and Respiratory, a network of clinical research sites that was formed to contract with sponsors to perform studies by principal investigators affiliated with its members and to market these services. Dynavax began a clinical study agreement with CRN March 31, 2005, for the trial of DV1-SAR-08, a drug intended to treat ragweed allergy in children. On April 12, 2005, CRN and SWI agreed to make SWI's service a trial site for the '08 study. On Dec. 20, 2005, CRN and Dynavax entered a clinical study agreement for the trial of DBV1-SAR-09, a medication for ragweed-allergic adults, and on Jan. 24, 2006, CRN and SWI executed an agreement that SWI would serve as a clinical research site for the '09 study.

On Feb. 23, 2007, Dynavax sent an e-mail to the investigators for the '08 and '09 studies advising them that it was terminating both studies early. SWI performed reconciliations for the '08 and '09 studies and found that it was owed $71,857 for the '08 study and $273,129 for the '09 study. On March 12, 2007, Dynavax informed SWI that it would not make payment based on the reconciliations. On May 27, 2009, SWI filed litigation against Dynavax and CRN alleging breaches of the '08 and '09 clinical study agreements between Dynavax and CRN by Dynavax, with SWI suing as a third-party beneficiary to those contracts.

Dynavax moved to dismiss SWI's case, arguing, in part, that because SWI's contract was with CRN and not Dynavax, SWI could not sue Dynavax for breach of contract. In a decision authored by Judge Joe Billy McDade, the court found that in arranging a contract for which Dynavax knew that a significant portion of its business would be conducted in Illinois, by an Illinois business, on Illinois residents, Dynavax ''purposefully availed'' itself of the benefits of Illinois. McDade also wrote that SWI had sufficiently alleged that it was an intended third-party beneficiary to the contracts between Dynavax and CRN to survive Dynavax's motion to dismiss.

The court denied Dynavax's motion, allowing the case to proceed with Dynavax as a defendant (9 MRLR 206, 4/7/10).

Neither SWI nor Dynavax responded to BNA's requests for comment.

The court order can be found at http://op.bna.com/hl.nsf/r?Open=jaqo-8hkjy6.

Clinical Trials

ClinicalTrials.gov Increases Transparency; Improving Subjects' Experience May Be Next

The clinical trials system has become increasingly transparent, partially due to laws requiring that results and other data go to a federal database, federal officials said June 7 at a National Institutes of Health conference, adding that they also want to improve how subjects enroll and participate in trials.

''The era of the 22-page consent form that nobody reads anyway is an era that needs to change,'' NIH Director Francis S. Collins said. ''I think we all agree—and it's certainly underway—to see what we can do to regain the true spirit of the Belmont Report in terms of what it means to have informed consent for participants in trials in a way that is meaningful and not just simply trying to check off a box.''

The National Library of Medicine within NIH hosted the conference, ''Clinical Trials: Present Challenges and Future Opportunities,'' on the NIH campus in Bethesda, Md. The event was the third in a series of NLM conferences, which have focused on personalized electronic health records, and last year explored the convergence of personalized medicine and centralized electronic health records. As the developer and manager of the largest clinical trials registry, ClinicalTrials.gov, NLM used the most recent conference to discuss how the website could be even more useful and to have a more general discussion of clinical trials and enhancing recruitment.

''We need to work on ways to make participation easier and more convenient, more transparent and less bureaucratic,'' Collins said.

Collins said NIH should be surveying all the ways in which it supports clinical trials and whether the agency is making wise choices, covering gaps that traditionally have been left unattended, and making sure any trial it funds has ''sufficient power'' to produce a meaningful result and is not too small in size to make that determination.

Jerry Menikoff, director of the Office for Human Research Protections (OHRP) in the Department of Health and Human Services, stressed the importance of partnerships with all the stakeholders in clinical trials, including institutional review boards, to improve the system for protecting research subjects.

''We are on the record as saying we encourage greater use of central IRBs, and we're partnering with as many partners as possible to improve the systems,'' he said.

More Collaboration Needed. He also talked about the importance of partnerships both in promoting research and the protection of those who enroll in these studies.

''Our goal is to make sure they're adequately protected,'' he said, referring to research subjects. ''At the same time, our goal is to support the appropriate researchers. Research is clearly important to all of us.''

Menikoff explained the Common Rule (45 C.F.R. Part 46), or the federal regulations to protect human subjects in research. He said about two-thirds of research institutions with a federalwide assurance with HHS—an agreement that the institution will comply with the regulations—have opted to ''check the box,'' or make

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the regulations apply to all research taking place at the institution, and not just the studies funded by the Public Health Service. Menikoff said there are about 7,000 IRBs that have registered with OHRP, and about a quarter of those institutions are located outside the United States.

The OHRP director described what he called three ''newish'' types of studies:

- electronic data collection from clinical records,
- community-based participatory research, and
- patient-driven digital health networks.

In terms of electronic data collection, Menikoff said clinical records provide huge amounts of data, and because the use of electronic medical records is increasing, it is easier to combine records for research purposes. Further, by not collecting identifiers, this process can be done outside the Common Rule because it would not be considered human subjects research and informed consent would not be required.

At the same time, Menikoff raised a number of ethical issues with electronic data collection, such as whether it is acceptable to collect these data without consent, if doing so protects the autonomy of the people whose data has been collected, issues of privacy and confidentiality, and the question of whether de-identified data truly are de-identified.

Community-based participatory research (CBPR), or research conducted as an equal partnership between traditionally trained ''experts'' and members of a community, raises both traditional and new ethical questions, he said. Traditionally, Menikoff said, there is the question of distinguishing the roles of community participants as researchers versus subjects of the research. The new ethical question is whether CBPR requires a different conceptual approach to ethical principles altogether. He asked whether because of the nature of the research, there should be a focus on protecting the group versus protecting individual subjects.

Menikoff said patient-driven digital health networks could help harness the Internet to give patients a more active role in clinical trials. For example, they can serve as a mechanism to recruit patients for standard trials, genomic trials, and even patient-centered interventions through websites such as PatientsLikeMe.com. At the same time, Menikoff said, there are ethical issues such as privacy and confidentiality, ensuring that there is a sound research design, and the role of researchers in endorsing experimental care.

Menikoff said it is fascinating to see how these issues will work out, and that it is encouraging to see possible changes out there in terms of ''getting rid of the burdens that make certain type of trials difficult.''

Quality Investigators Most Important. Deborah Zarin, director of ClinicalTrials.gov, highlighted some of the latest efforts of the registry, including the results database established in 2008 as part of the requirements under the Food and Drug Administration Amendments Act of 2007 (Pub. L. No. 110-85) (7 MRLR 394, 7/2/08).

''Sunshine may lead to improvements; the quality of the data will depend on the quality of the investigators,'' Zarin said.

Suppressing research results impedes all parts of science, Zarin said, but this is particularly problematic for clinical trials because they depend on human volunteers and results are used to inform medical decisions for the general public. She identified three key problems in data suppression: not all trials are published, publications do not always include all of the outcomes' measures, and there is not always the acknowledgement that such changes occurred.

When initially posting information on the results database, Zarin said, her team did not anticipate there would be much of a need to check the validity of the data.

''It turns out there are many opportunities,'' she said. ''We know that the mean age can't be 624 years. We don't know if it was 62.4 or 6.24.''

She cited another recent example, in which the data had more eyeballs than two times the number of people in the study.

''Please explain the origin of the 12 extra eyeballs,'' she said to laughter.

Zarin underscored that scientific journals do not reject manuscript submissions based on a ClinicalTrials.gov entry.

''This complements, it doesn't replace, journal publication,'' she said. ''You can use ClinicalTrials.gov to identify trials of potential interest and track what's going on with a particular trial.''

BY JEANNIE BAUMANN

More information on the NLM conference is available at http://bit.ly/kaNeGV.

Technology Transfer

Bill Seeks Study of Government Royalties For Developed Federally Funded Research

Rep. Chaka Fattah (D-Pa.) introduced legislation May 26 that would establish a commission to study the possibility of collecting government royalties on commercialized, profitable products that resulted from federally funded research.

The American Discoveries-American Jobs Commission Act of 2011 (H.R. 2015) further would direct the commission to ensure that products developed with federally supported research are manufactured in the United States.

According to a statement from Fattah's office, the federal government spends about $130 billion annually on research and development to assist federal agencies in their duties (the American Association for the Advancement of Science estimated $144.4 billion for fiscal year 2011). Fattah's statement said that under existing statutes, royalties derived from intellectual property rights give the academic community an alternative way to support further research and the business sector a way to get a return on its financial contribution. While he did not name it specifically, the 1980 Bayh-Dole Act (Pub. L. No. 96-517) grants patent rights for inventions arising from government-sponsored research and development to certain types of entities to encourage the commercialization of new technologies through cooperative ventures involving the research community, small business, and industry.

Fattah argued that ''the federal government should be given the same consideration.''

''The Federal government should be able to claim royalties from its own investment in early research then reinvest those royalties in science, technology, engi-

neering and math education and future federal research,'' Fattah said in a May 18 statement. ''If new or improved products are on the commercial market because of federal research dollars then they should be stamped 'Made in America.' ''

WARF Counsel Comments. Howard Bremer, emeritus patent counsel at the Wisconsin Alumni Research Foundation (WARF) whose advocacy efforts helped lead to passage of Bayh-Dole, told BNA June 6 that this type of legislation has been proposed in the past.

He noted that while the government provides funding for basic research, the cost to develop and commercialize the technology is at least 10 to 100 times the cost of the initial research. ''When you look at the dollars that they're supporting now a year for basic research, the royalty returns would literally be a drop in the bucket,'' Bremer said.

He said that any additional revenue made by universities under the Bayh-Dole Act already goes towards education and additional research.

''The inventor gets a share, and then costs can be recovered. But then any remaining monies over that already are directed into research by the universities that administer the Bayh-Dole Act within each of their own provinces,'' Bremer said. ''Having that go into a general government funding, I think it's just going to be lost. Here it's directed for a very specific purpose, and as a consequence, I think can do much more good than just returning some of the monies back to the general fund where who knows what it'll be spent for?''

Fattah's bill has been referred to the House Committee on Science, Space, and Technology.

The full text of the American Discoveries-American Jobs Commission Act of 2011 (H.R. 2015) is at http://www.govtrack.us/congress/billtext.xpd?bill=h112-2015.

Research Ethics

Judge Dismisses Some Claims in Vets' Suit But Lets Others Against CIA, DOD Continue

SAN FRANCISCO—A federal judge May 31 dismissed in part a putative class-action lawsuit alleging the Central Intelligence Agency and the Defense Department drugged and exposed unwitting soldiers to toxins in medical experiments run over decades (*Vietnam Veterans of America v. Central Intelligence Agency*, N.D. Cal., No. 4:09-cv-00037, *case referred to magistrate for discovery*, 6/1/11).

While dismissing the plaintiffs' Administrative Procedures Act claims for medical care and notice against the CIA, Judge Claudia Wilken of the U.S. District Court for the Northern District of California denied defendants' motion to dismiss the case. As such, constitutional claims still stand, with plaintiffs seeking medical care and admission of harm. It was the third time the government has tried to dismiss the case since it was filed in 2009.

Plaintiffs did not object to dismissing claims against Attorney General Eric Holder. Wilken ordered the Department of Veterans Affairs and VA Secretary Eric Shinseki to answer the complaint within 14 days of the May 31 order.

More of the Same. The soldiers alleged the government failed to honor promises to locate and give treatment to those who were subjected to human experimentation.

Plaintiffs' lead counsel Gordon Erspamer of Morrison & Foerster said that ''nothing at the VA has changed as far as we can tell.''

The VA still denies ''virtually all the claims by soldiers'' in the chemical and biological weapons tests, Erspamer said in a June 3 e-mail to BNA.

''All the defendants pursue tactics intended to cause delay, and continue to refuse or search for key categories of documents,'' he said, adding that the defense strategy is to continue ''delaying, trusting that most of the 'greatest generation' will die before the day of justice happens.''

A Department of Justice spokesman June 6 declined comment on the matter.

Long-Running Program. Vietnam Veterans of America, Swords to Plowshares, and Army veterans in January 2009 sued the CIA and the departments of Defense and the Army, claiming a decades-long program of subjecting unaware individuals to drug testing, gas poisoning, riot control agents, and narcotics that caused lasting injuries (8 MRLR 45, 1/21/09).

From the 1950s to the mid-1970s, about 7,800 soldiers volunteered to participate in experiments, including drug tests, tests on the effects of chemical and biological weapons, and research on mind-control methods, plaintiffs said.

Plaintiffs said the volunteers participated without giving informed consent because the risks of the experiments were not fully disclosed, despite an Army memo and regulation and in violation of the 1947 Nuremberg Code on medical research.

Wilken last year dismissed in part and sustained in part the veterans' suit (9 MRLR 85, 2/3/10).

Erspamer said he anticipates the government ''will dress up and re-file basically the same motions'' as part of its summary judgment motion.

A further case management hearing is scheduled for Jan. 5, 2012, with a bench trial scheduled for March 26, 2012.

A CIA spokeswoman contacted by BNA declined to comment on the ruling.

Plaintiffs are represented by Erspamer, Timothy W. Blakely, Adriano Hrvatin, Kimberly L. Taylor, and Stacey M. Sprenkel, of Morrison & Foerster, San Francisco.

The government is represented by Joshua Edward Gardner, Kimberly L. Herb, Brigham Bowen, Judson O. Littleton, and Lily Sara Farel, of the U.S. DOJ Civil Division, Federal Programs Branch.

BY JOYCE E. CUTLER

Social and Behavioral Research

Coburn Decries NSF Management, Programs, Wants to Eliminate Social Science Funding

Sen. Tom Coburn (R-Okla.) May 26 issued a critical report on the National Science Foundation, concluding that it has ''pervasive problems'' in waste, duplication, and oversight issues, and called for eliminating NSF's social sciences program.

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''There is no question NSF serves an important—and legitimate—purpose in our society and has contributed to scientific discovery. As the NSF accurately notes, advances like the Internet, cloud computing, bar codes and magnetic resonance imaging technology were supported with investments from NSF,'' Coburn said in a statement. ''Unfortunately, in some ways NSF has undermined its core mission through mismanagement and misplaced priorities. For instance, spending taxpayer dollars to study why some college basketball teams dominate March Madness, funding trips for romantically-involved NSF employees and duplicating programs contributes to our debt rather than science.''

NSF issued a statement in response to the senator's report that ''no other funding agency in the world comes close to NSF for giving taxpayers the best return on their investment.'' According to data from the American Association for the Advancement of Science, NSF received $6.8 billion in fiscal year 2011, or about 4 percent of the nation's total research and development portfolio.

One week after Coburn issued his report, a House Science subcommittee held a hearing on the importance of the social sciences program that Coburn had proposed to eliminate.

''The social, behavioral, and economic sciences—familiarly known as the SBE sciences—increase fundamental understanding of human social development and interaction and of human behavior, as individuals and as members of groups and more formal organizations,'' Myron P. Gutmann, assistant director of the SBE directorate at NSF, said during the June 2 House hearing. ''Our sciences contribute knowledge that has societal relevance and can inform critical national areas such as job creation, health care, education, public safety, law enforcement, and national security, among others.''

Coburn released the report, ''The National Science Foundation: Under the Microscope,'' amid plans by the Obama administration to double funding for three sciences agencies, including NSF (10 MRLR 349, 5/18/11). The plan is part of a White House goal to bring the nation's investment in research and development up to 3 percent of U.S. gross domestic product to maintain the nation's competitiveness in the sciences.

''Spending more money alone will not ensure America's success in science. We need to target the money we spend wisely to realize meaningful scientific discoveries and advances. This report takes a closer look at whether or not NSF is succeeding with this goal,'' Coburn's report said.

Coburn's Findings. Coburn's report included several findings, including the acknowledgement that NSF has an important mission and contributes to meaningful scientific discovery, but that there are pervasive problems at the agency. His report also said NSF lacks adequate oversight of its grant funding, which he said has led to mismanagement, fraud and abuse, and a lack of knowledge regarding research outcomes; that it is prone to extensive duplication within the agency and across the federal government; and that NSF ''wastes millions of dollars'' on low-priority projects.

The report found NSF lost more than $1.2 billion due to waste, fraud, duplication, and mismanagement in fiscal year 2010. It also cited other examples of mismanagement, including: hundreds of millions of dollars lost to ineffective contracting; $1.7 billion in unspent funds sitting in expired, undisbursed grant accounts; at least $3 million in excessive travel funds; and a lack of accountability or program metrics to evaluate spending.

In his report, Coburn offered several recommendations, including:

- Establish clear guidelines for what constitutes ''transformative'' and ''potentially transformative'' science, a process he acknowledged the agency has begun but that he said needs more work to evaluate the merit of each project the agency funds.
- Set clear metrics to measure success and standards to ensure accountability because the agency needs to improve its grant administration and evaluation mechanisms.
- Eliminate NSF's Social, Behavioral, and Economics (SBE) Directorate ($255 million in FY 2010).
- Consolidate the Directorate for Education & Human Resources ($872 million in FY 2010), which focuses on science, engineering, education, and math (STEM) development and training. The report said there are nearly 100 federal STEM programs administered by 11 federal agencies, including NSF.
- Return $1.7 billion of unspent, expired funds it holds.
- Develop a strategic plan to streamline federal research and development.
- Give the NSF inspector general additional resources and place a greater emphasis on the office of inspector general's findings.

Social Sciences Recommendation Repeat of 2009 Effort. The recommendation to eliminate social science funding echoes an effort from Coburn two years ago. In October 2009, Coburn offered an amendment to a bill on hiring incentives ''to redirect funding of the National Science Foundation toward practical scientific research,'' which would have prohibited NSF from funding any political science-related grants. The Senate ultimately defeated Coburn's amendment 36-62 in November 2009.

''The social sciences should not be the focus of our premier basic scientific research agency,'' a statement from Coburn's office said May 26.

In a June 1 statement, the Association of American Universities said the research supported by SBE is critical to addressing some of the most important issues facing society.

''Finding solutions to national problems ranging from addressing our economic challenges to achieving energy independence, from combating obesity and other diseases to combating terrorism, requires the kind of research funded by this directorate. Eliminating it would diminish our country's ability to address these and other critical issues,'' AAU said.

NSF: Peer Review Process 'Gold Standard.' In its response, NSF defended its peer review process used for more than 40,000 proposals each year, and said discoveries and innovations that have resulted from NSF-funded research have advanced the frontiers of science and engineering, improved Americans' lives, and provided the foundations for countless new industries and jobs.

''The National Science Foundation is renowned for its gold-standard approach to peer review of each of the more than 40,000 proposals it receives each year,'' the NSF statement said. ''While no agency is without flaws,

NSF has been diligent about addressing concerns from members of Congress about workforce and grant management issues.''

The NSF statement said the agency has pursued cases of wrongdoing; terminated and even turned over for criminal prosecution employees found to have violated NSF rules or laws; and collected and returned to the U.S. Treasury any fraudulently used funds.

''We believe that no other funding agency in the world comes close to NSF for giving taxpayers'' the best value, the agency statement said.

Gutmann said during the House hearing that ''NSF's review processes remain, in the words of the National Academies, among 'the best procedures known for insuring the technical excellence of research projects that receive public support.' ''

Multi-Year Awards. The $1.7 billion cited by Coburn is related to the grant-making process and multiyear nature of the awards. Because most NSF grants are three to five years in length, NSF explained that for research and related activities, Congress gives NSF two years to spend the money, and a university has the authority to draw those funds for up to five years afterward. Federal appropriations law requires that if all of the funds are not drawn down by the university in that seven-year period, the funds are canceled and returned to the U.S. Treasury, according to NSF.

''If NSF makes an award out of this year's budget, an award of $1 million for example, the university researcher spends about $200,000 of that per year,'' the agency said. ''The $1.7 [billion] in undisbursed grant balances as of September 30, 2010, represents the amount NSF grantees have been awarded but have not yet spent.''

NSF typically returns $20 million to $30 million per year to the U.S. Treasury, the agency said.

''That balance is evidence of appropriate bookkeeping and spending practices, not of waste,'' NSF said.

AAU also defended the multiyear grant process and NSF's bookkeeping for it.

''It is disconcerting to see a Congressional report misrepresent NSF's multi-year granting process in a way that makes this efficient agency look profligate,'' AAU said. ''The report suggests that peer reviewed, multiyear grants awarded to scientists are somehow being wasted or should be returned to the Treasury. In fact, NSF research grants are typically forward-funded for three to five years to ensure stable and efficient support that is not disrupted by the annual appropriations process. This is smart stewardship of taxpayers' dollars.''

University Association Defends NSF's Record. Further, AAU said, Coburn's report undermines NSF's record in research and marginalizes NSF-supported science that ''helps to make our country strong.'' The association noted that the White House Office of Management and Budget consistently has given the agency high marks for management over the past decade.

AAU described Coburn's report as distorting ''real and useful'' science.

''It is all too easy to make specific research sound 'funny' and therefore wasteful. However, the grants cited in the report were peer reviewed and are intended to address real societal challenges and scientific issues,'' AAU said. ''Sometimes the 'funniest' sounding research leads to important discoveries that improve our health, grow our economy, or ensure our national security.''

Coburn's report cited examples of NSF-backed studies he felt were questionable, such as researchers at the University of California Berkeley who developed an autonomous robot to fold reliably piles of towels.

''[T]he development of a robot that folds towels is actually an important step in producing a new generation of robotic devices that could, according to its lead researcher, . . . increase the independence of elderly and sick people and protect our soldiers in combat,'' AAU said.

House Panel Touts Importance of SBE. The June 2 hearing held by the House Science, Space, and Technology Subcommittee on Research and Science Education addressed the need for social, behavioral, and economic sciences as well as a review of funding for that NSF directorate.

Rep. Daniel Lipinski of Illinois, the top Democrat on the subcommittee, said he was particularly interested because he is a social scientist.

''Reasonable people might disagree about priorities within the SBE Directorate, and because of my own academic experience, I too might single out a grant here and there as being of questionable value. It is certainly our job to be vigilant and to have these debates to ensure that taxpayer dollars are being spent wisely,'' Lipinski said in a June 2 statement. ''But I also believe that NSF does an excellent job overall of identifying and funding outstanding research, and I hope we are prepared to have a rational discussion about the value of SBE sciences to our society and to the taxpayer.''

Lipinski expressed caution about what he called ''the dangers of politicians trumping the merit review system to decide which grants should and should not be funded.''

Peter Wood, president of the National Association of Scholars, said in testimony that the decision to create NSF (in 1950) as a way to advance basic research is as good an idea today as it was back then.

''We need basic research not least because it is the deep source of almost all our technological and economic progress.'' Wood said. ''The better reason to fund the SBE sciences through the NSF is to sustain scientific excellence. . . . Without a national commitment to such excellence, we will end up a hollow civilization: one that values knowledge of mechanics of things disconnected from our knowledge of ourselves.''

By Jeannie Baumann

Coburn's report, ''The National Science Foundation: Under the Microscope,'' is available at http://1.usa.gov/mT7gtb.

The senator's 2009 amendment is available at http://1.usa.gov/4dwQg1.

More information on the House subcommittee hearing is available at http://science.house.gov/hearing/subcommittee-research-and-science-education-hearing-social-bahavioral-and-economic-science.

AAU's statement on the societal benefits of basic research is available at http://www.aau.edu/research/societal_benefits.aspx.

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Insurance Coverage

District Court Upholds Denial of Coverage For Experimental Treatment in Clinical Trial

ST. LOUIS—A federal court May 31 upheld a health plan's refusal to cover the costs of a Crohn's disease patient's participation in a clinical trial investigating the use of a stem-cell-transplant treatment for the disease (*Parsons v. Sisters of Charity of Leavenworth Health System Inc.*, D. Mont., 1:10-cv-47, *summary judgment granted* 5/31/11).

The court granted summary judgment to the Sisters of Charity of Leavenworth Health System, which operates a self-funded employee medical plan, ruling that the plan and its administrators did not abuse their discretion in denying coverage for a treatment that plan administrators had concluded was investigational, experimental, and not medically necessary.

The court noted that the physician conducting the clinical trial had acknowledged the need to test the efficacy of the treatment with randomized trials, that three independent reviewers had affirmed the denial of coverage, and that the consent form signed by the plaintiff for admission into the trial stated that the treatment was experimental and of no proven benefit.

''Although the Court is very sympathetic to [the plaintiff's] situation, Defendants' plan clearly excludes coverage for services and supplies that are experimental and investigational,'' Judge Richard Cebull of the U.S. District Court for the District of Montana said. ''The record reveals several reasons to conclude Defendants did not abuse their discretion in denying Plaintiffs' request for coverage for [the] clinical trial.''

Denial of Coverage. The lawsuit was filed by Randee Parsons, a 20-year-old patient with Crohn's disease, a severe autoimmune disease that inflames and attacks the gastrointestinal tract, the ruling said. Recently, treatment of Crohn's disease with autologous bone marrow transplants (ABMT), a type of stem-cell-transplant treatment, has produced promising results, it said. Parsons sought and was granted admission into a clinical trial investigating the treatment of Crohn's disease with ABMT techniques. The trial is being conducted by Richard Burt, a physician and immunologist at Northwestern Medical School.

Parsons was covered under a medical plan issued to her mother as an employee of St. Vincent Healthcare Hospital in Billings, Mont., which is part of the Sisters of Charity of Leavenworth Health System. The plan is administered by Blue Cross and Blue Shield of South Carolina Foundation, also a defendant in the lawsuit.

According to Cebull, Parsons sought coverage for the clinical trial in December 2009, and was denied by BCBS administrators in February 2010 on the grounds that the treatment used in the trial was ''investigational and experimental'' and not medically necessary.

Parsons then appealed the denial to the Sisters of Charity Benefits Administration Committee, which sought external independent review from gastroenterologists who had experience treating Crohn's disease. The reviewers noted that only a few Crohn's disease patients had been treated with ABMT techniques, and concluded that the clinical trial was investigational and experimental, upholding the denial of coverage. Parsons then appealed a second time to the Benefits Administration Committee and was turned down again.

Having exhausted her administrative remedies, Parson filed a lawsuit in federal court, alleging breach of fiduciary duty, negligent utilization review, breach of insurance contract, causation, and violation of Montana's Unfair Claim Settlement Practices Act.

Lawsuit Claims Abuse of Discretion. The crux of the lawsuit was whether the defendants abused their discretion in denying coverage to Parsons for participation in the clinical trial, Cebull said.

Cebull first turned to the consent form for the clinical trial that all participants, including Parsons, were required to sign. The form was replete with terms such as ''experimental,'' ''research,'' and ''study,'' which made clear that the trial was ''risky, of no proven benefit, and may not work,'' Cebull said.

In addition, the language of the form ''implicitly recognizes'' that ABMT treatment is not standard for Crohn's disease, and even distinguishes between the treatment offered in the study and ''standard treatment'' for the disease, Cebull said.

Cebull also noted that the plaintiffs' response briefs and supplemental brief failed to discuss the ''problematic nature this consent form has to Plaintiffs' claims.''

''From the consent form alone this Court concludes that Defendants did not abuse their discretion in denying coverage on the grounds that the clinical trial was experimental and investigational and not medically necessary,'' Cebull said.

Cebull next turned to Burt's peer-reviewed literature regarding ABMT treatment for Crohn's disease, which Parsons had submitted to the Benefits Administration Committee in appealing the denial of coverage. That literature did not establish that the treatment was not experimental and investigational, Cebull said, and even contained Burt's admission that the effectiveness of ABMT treatment for the disease needed to be confirmed by randomized trials.

The plaintiff also claimed that the defendants should not have used gastroenterologists to review denial of coverage for the clinical trial, because ''a gastroenterologist is not qualified to review ABMT treatments for Crohn's disease,'' Cebull said. Instead, the plaintiffs argued that the defendants should have turned to a hematologist or transplant specialist familiar with bone-marrow transplants to review the request for coverage.

But this argument amounted to an attempt by plaintiffs to ''have it both ways,'' Cebull said, to characterize the ABMT treatment both as a recognized therapy for Crohn's disease, and one that was beyond the expertise of gastroenterologists to evaluate. ''The fact that Plaintiffs argue Defendants' gastroenterologist reviewers are not qualified to review their request for coverage reflects how far afield the use of ABMT treatment is from generally accepted Crohn's disease treatment,'' Cebull said.

''If, as Plaintiffs would like this Court to hold, ABMT is a recognized and non-experimental therapy for Crohn's disease, then the independent gastroenterologist reviewers should be qualified to review Plaintiff's claims for coverage,'' he wrote. ''For these reasons, the Court cannot conclude that Defendants abused their discretion in having gastroenterologists independently review the request for coverage.''

An attorney for Parsons was not available for comment.

BY CHRISTOPHER BROWN

The court's decision is available at http://op.bna.com/hl.nsf/r?Open=psts-8hsrce.

Insurance Coverage

Appeals Court Finds No Abuse of Discretion By Plan That Denied Brain Tumor Treatment

A health plan acted reasonably in concluding that a beneficiary's proposed brain tumor treatment was not covered because it was experimental or investigational, a federal appeals court ruled June 7 (*Lafferty v. Providence Health Plans*, 9th Cir., No. 10-35688, *unpublished* 6/7/11).

The U.S. Court of Appeals for the Ninth Circuit, in an unpublished decision, said Providence Health Plans did not violate the Employee Retirement Income Security Act in holding that a proposal to treat a beneficiary's rare, malignant brain tumor with interarterial chemotherapy with blood brain barrier disruption (BBBD) was not covered by her health plan.

The Ninth Circuit reversed a decision by a federal trial court that found, after engaging in de novo review, that the treatment sought by Joan Lafferty was a covered benefit because it was a ''medically necessary service.'' The trial court rejected the plan's ''experimental or investigational'' defense, based on evidence Lafferty presented concerning the use of such treatment to treat her condition, primary central nervous system lymphoma (PCNSL).

The trial court noted that:

- BBBD-enhanced chemotherapy was used at six specialized U.S. medical centers and in the local medical community;
- all treatments for PCNSL are under continued research and treatment because the disease is so rare there have been no phase II trials for its treatment;
- there are differing opinions as to its effectiveness over chemotherapy alone or with radiation; and
- the Centers for Medicare & Medicaid Services has stated that BBBD used as part of a treatment is acceptably safe (9 MRLR 273, 5/5/10).

De novo review was appropriate, the trial court found, because of irregularities in the way Lafferty's appeals were handled. It noted in its April 2010 decision that several individual health care providers involved in making the initial coverage decision were improperly involved in considering Lafferty's appeals. The court refused to reconsider that decision two months later (9 MRLR 399, 7/7/10).

Erroneous Standard Applied. The trial court's decision to engage in de novo review, rather than to apply an abuse of discretion standard to the plan's coverage determination, was erroneous, the Ninth Circuit said. ''The exception to deferential review of the decisions of plan administrators does not apply in this case,'' the Ninth Circuit said.

''Although there are some troubling aspects to Providence's review of Lafferty's initial grievance and subsequent appeals,'' they did not amount to a ''wholesale and flagrant disregard of ERISA procedural requirements'' required in the Ninth Circuit to warrant application of de novo review, the appeals court said.

Applying the abuse of discretion standard to the record in the case, the Ninth Circuit said that it did ''not discern implausibility or the absence of logic in Providence's decision to deny coverage.'' Rather, ''Providence's conclusion that Lafferty's treatment was experimental, and therefore not covered, is supported by facts in the record,'' it said.

Lafferty was represented by Megan E. Glor, Portland, Ore. Providence was represented by Arden J. Olson and Sharon A. Rudnick, of Harrang Long Gary Rudnick PC, Eugene, Ore.

The court's decision is at http://op.bna.com/hl.nsf/r?Open=psts-8hptca.

Effectiveness Research

Officials Say Patient Engagement Key To Successful Comparative Effectiveness

For comparative effectiveness research (CER) to be successful, patients must be an integral part of the research process, government officials said during a June 8 panel discussion held by the Friends of Cancer Research.

Carolyn Clancy, director of the federal Agency for Healthcare Research and Quality, said the first step to successful CER is to identify the questions that need answering. She said the first tier of CER is not so much about identifying which drug or medical device would work best with which condition but about understanding what patients want.

''It's much more about getting to the right questions. The point is the process—how do we get to finding out what patients need?'' Clancy said.

Clancy is part of the Board of Governors for the Patient Centered Outcomes Research Institute (PCORI), a nonprofit organization established as a part of the health care reform legislation that is tasked with carrying out comparative clinical effectiveness research. The Government Accountability Office appointed the 19-member board of governors for PCORI in September 2010 (9 MRLR 614, 10/6/10).

The Patient Protection and Affordable Care Act establishes a permanent funding stream for CER that, once fully implemented, will generate about $600 million annually for PCORI research priorities.

The goal of the institute is to assist patients, clinicians, purchasers, and policymakers in making informed health decisions by using evidence-based medicine. The PCORI board includes a diverse array of members from patient and consumer organizations, drug and medical device companies, insurers and providers, and academia.

Francis Collins, director of the National Institutes of Health and another member of the PCORI board, said during the forum that the fact PCORI is made up of different types of stakeholders should make it easier for agencies to collaborate .

''The big task is to find out what [studies] have been done, what's being done, and what needs to be done,'' Collins said. The best way to do that, he said, is to invest in research at the patient level. PCORI ''won't focus on disease x or y'' at least at first, he said. It needs

to focus on ''putting together teams to give feedback on what patients are interested in, what drives results.''

Collins said PCORI will not dispense ''disease specific'' grants for ''quite a few months.''

Janet Woodcock, director of the Food and Drug Administration's Center for Drug Evaluation and Research, said during the forum that the best way to engage patients is to take the research directly to the communities and out of a medical setting. She said it is cheaper, and more effective, since patients would be more responsive if they were an active part of the solution.

BY NATHANIEL WEIXEL

More information about PCORI is at http://www.pcori.org/.

Intellectual Property

Court Declines to Dismiss Dueling Claims Of Infringement by Alzheimer's Organizations

Two organizations focused on work related to Alzheimer's disease have pleaded dueling claims of trademark infringement against each other sufficient to survive motions to dismiss, the U.S. District Court for the Southern District of New York ruled May 25 (*Alzheimer's Foundation of America Inc. d/b/a Alzheimer's Foundation v. Alzheimer's Disease and Related Disorders Association Inc. d/b/a Alzheimer's Association,* S.D.N.Y., No. 1:10-cv-03314-RWS, 5/25/11).

Granting in part the parties' motions to dismiss, the court noted that the dispute arose from one organization's claim that the other illegitimately accepted a contribution from an estate not meant for it.

Both Parties Hold Trademark Registrations. Alzheimer's Foundation of America Inc. d/b/a Alzheimer's Foundation, founded in 2002, is a New York-based not-for-profit group involved in offering support services to Alzheimer's patients. The foundation solicits charitable contributions and donations to support its operations.

The foundation holds several U.S. service mark registrations for logos and images combined with phrases including the term ''Alzheimer's Foundation.''

Alzheimer's Disease and Related Disorders Association Inc. d/b/a Alzheimer's Association is another entity focused on funding research into Alzheimer's disease and offering support services to patients. The association holds a registered service mark for the term ''Alzheimer's Association.''

According to the complaint, in 2003, a trust called the Mildred E. Harbaugh Living Trust was created that included a provision to distribute 15 percent of the estate to the Alzheimer's Foundation. Harbaugh died in 2005 and her trust issued a check for $36,000 to the Alzheimer's Foundation. However, the foundation alleged that the association accepted the check and deposited it in its own account. The foundation claimed that the association similarly endorsed and converted other checks intended for the foundation, in the amount of $20, $10, and $5.

The foundation brought an action in Virginia state court, which issued a judgment determining that the $36,000 check belonged to the association.

The foundation sued the association in federal court, alleging violations under the Lanham Act and New York state statutory and common law. According to the foundation, in accepting, endorsing, and depositing checks, the association had held ''itself out to the world as the rightful owner of the Foundation's Marks'' and created the impression ''that the Association and the Foundation are one and the same.'' The association then initiated another proceeding, bringing several claims against the foundation, including claims of trademark infringement.

Both parties moved to dismiss under Fed. R. Civ. P. 12(b)(6) for failure to state a claim for which relief may be granted.

Pleadings Sufficient to Survive Dismissal. Judge Robert W. Sweet first denied the motion to dismiss with respect to both parties' claims under the Lanham Act and the claims of dilution and unfair competition.

The court noted that the foundation had alleged legitimate interest in four marks, sufficient to make a prima facie trademark case. The association argued that the foundation had not alleged that the association had used both the graphic and word portions of its registered marks.

''While a composite mark (consisting of both a word element and a design element) must be considered in its entirety, trademark law recognizes that the word portion is often more likely to be impressed upon a purchaser's memory because it is the word that purchasers use to request the goods and/or services,'' the court said. ''Therefore, the word portion is often accorded greater weight in determining the likelihood of confusion.''

The court also suggested that there exists a ''compelling reason for the enhanced judicial protection of a charity's trademarks in ensuring their contributions to charitable organizations are received by the correct charity.''

With regard to the mirroring trademark claim against the foundation, the court noted that the association also had a legitimate claim based on a registered trademark.

The foundation argued that the association could not establish a claim under *Miss World (UK) Ltd. v. Mrs. America Pageants Inc.*, 856 F.2d 1445 (9th Cir. 1988). The court pointed out that in this case, unlike in *Miss World*, both parties alleged a likelihood of confusion caused by their use of their respective marks. Thus, here there was an agreement that a likelihood of confusion existed. Furthermore, the court noted that *Miss World* found that the marks at issue had elements that distinguished them from each other.

''The term 'Alzheimer's Foundation' does not include any connecting words to comparably distinguish itself from the Association's mark,'' the court said.

Thus, the court declined to dismiss the association's trademark infringement claim. Furthermore, the court found that its dilution claim had been adequately pleaded as to survive dismissal.

State Court Decision Estops UCC Claim. However, with respect to the $36,000 check, the court did dismiss the foundation's claims of conversion and conspiracy and its claim under the Uniform Commercial Code, N.Y. U.C.C. Law § 3-404, which renders inoperative any unauthorized signature. The Virginia state court's judgment estopped any further claims in this line, the court said.

The smaller checks were all sent to the association by individuals connected with the foundation, in an attempt to create evidence that the association was deceiving members of the public into believing that it was the foundation.

''The checks were intentionally addressed and delivered to the Association, the donors obviously intended for the Association to accept and deposit the checks,'' the court said.

Also dismissed was the foundation's claim of unjust enrichment, which was unsupported by sufficient allegations on the foundation's part.

The foundation was represented by Blair C. Fensterstock of New York. The association was represented by Joseph R. Robinson of McDermott Will & Emery, New York.

BY ANANDASHANKAR MAZUMDAR

Text of the opinion is available at http://pub.bna.com/ptcj/1003314May25.pdf.

Pediatric Research

GAO Faults FDA Tracking Procedures For Pediatric Drug Studies in New Report

The Food and Drug Administration should ''move expeditiously'' to track applications of drugs that are studied for use in children from beginning to end and maintain aggregate data on the process, the Government Accountability Office said in a report issued May 31.

FDA's failure to track and aggregate data from drug applications subject to the Pediatric Research Equity Act (PREA) has slowed down its review processes and possibly delayed dissemination of important pediatric study results, GAO said in *Pediatric Research: Products Studied under Two Related Laws, but Improved Tracking Needed by FDA* (GAO 11-457). According to the report, at least 130 drug and biological products have been studied in pediatric populations under PREA and the Best Pharmaceuticals for Children Act (BPCA) since the two laws' 2007 reauthorization, and those studies have led to important labeling changes.

Those labeling revisions could be considered an indication of the laws' success in fostering pediatric studies. However, GAO said that while an application subject to PREA is not complete unless it contains either pediatric study results or a request for a waiver or deferral of such a study, FDA does not track whether these items are included until FDA's Pediatric Review Committee (PeRC) evaluates the material. The report noted that the 2007 reauthorization of PREA established PeRC as an internal FDA committee responsible for providing assistance in the review of pediatric study results and increasing the consistency and quality of such reviews across the agency.

GAO said it was told by FDA officials that the PeRC generally does not review information about pediatric studies submitted with the application until near the end of the process, which can take as long as 300 or more days. This leaves FDA staff uncertain until the agency has almost completed review of an application about how many applications FDA receives are in fact subject to PREA, how many of those applications include the required pediatric studies, or how many applications make requests for waivers or deferrals.

GAO conducted the study in response to the mandates of PREA and BPCA. PREA requires that sponsors conduct and submit pediatric studies for certain products unless FDA grants them a deferral or waiver, although BPCA's recommendations are voluntary for sponsors.

For its report, GAO looked into how many and what types of products have been studied; described the number and type of labeling changes and FDA's review periods; and discussed challenges identified by stakeholders in conducting studies. GAO examined data on the studies from the 2007 reauthorization of PREA and BPCA through June 2010, reviewed statutory requirements, and interviewed stakeholders and agency officials for the study.

Need for Guidance. Stakeholders' opinions also were included in the report, and GAO said a significant problem was that FDA has provided little or no recent guidance about how to comply with mandates of PREA and recommendations of BPCA. The report noted that FDA officials admitted that for PREA the most recent guidance from the agency was draft guidance issued in 2005, while nothing has been issued for BPCA since 1999.

FDA officials told GAO that updated guidance was in the offing for both PREA and BPCA, but also said they have not established a schedule for promulgating such guidance. Informal discussions about timelines can be discussed with individual sponsors during the review process, FDA officials told GAO.

Another concern is that the five-year window of reauthorization of the two laws has prompted uncertainty. Given that both PREA and BPCA can be reauthorized every five years, some of the statutory requirements for studies could change while studies are in progress or as they are being planned, which has led to unease as to what will be required when studies actually are conducted. Two drug companies stated this uncertainty makes it difficult to know what will be involved in developing products for use in children over the long term, making planning a problem. For example, GAO said that since BPCA's reauthorization in 2007, FDA has taken an average of six years from start to finish in its review of the 50 drugs for which it has completed the review process.

Stakeholders also told GAO that they face yet another regulatory hurdle because they must comply with U.S. drug laws, the different requirements of PREA, and the European Union's (EU) Paediatric Regulation because they typically apply for approval of drugs or biological products in both the EU and the United States at the same time, GAO said in the report. For example, in the EU, a sponsor's plan for a product study in pediatric populations must be approved by the European Medicines Agency before studies are conducted, while in the United States in these situations, sponsors do not have formal contact with FDA regarding study design for studies submitted under PREA until the completed results are submitted to FDA. These variations leave sponsors unsure if studies done to comply with the European rules will meet FDA requirements.

Finally, GAO said, stakeholders complained about the lack of economic incentives, which affect sponsors' willingness to conduct pediatric studies voluntarily un-

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der BPCA. Stakeholders also told GAO drug and biological products that are off-patent or nearing the end of their market exclusivity are among the least likely to be studied in pediatric populations because sponsors stand to gain nothing economically in doing such studies. Once a drug or biological product is off-patent, the sponsor cannot receive pediatric exclusivity for conducting pediatric studies, which led to BPCA's giving the National Institutes of Health responsibility for awarding funds to entities that have the expertise and ability to conduct studies of off-patent drugs and biologicals, although these funds also are limited.

FDA, Others Respond to GAO's Report. FDA's parent agency, the Health and Human Services Department, agreed that better tracking of information is needed but disagreed with GAO's finding that it does not already track applications. In the report itself, HHS noted that FDA's Center for Biologics Evaluation and Research has a specific code in its Regulatory Management System for Biologics Licensing Application that allows it to track PREA-filed applications for biological products and asserted that FDA's Center for Drug Evaluation and Research can track the status of any application at any given time. GAO noted, however, that its recommendation was not based on FDA's ability to determine the status of individual applications, but rather its lack of aggregate data on applications that are subject to PREA during its review of the applications so as to be able to better manage its review process.

In the report, GAO said FDA could not determine how many of the applications that had been filed since PREA's 2007 reauthorization actually were subject to PREA. It reiterated that FDA's lack of aggregate data about an important program designed to enhance the safety of drug and biological products for use in children is inconsistent with sound internal controls.

In its comments, HHS stated that in May 2011, FDA improved its document tracking system in ways that will enable FDA to do a better job of tracking future applications that are subject to PREA. GAO noted that the comments failed to state whether the improvements will allow FDA to determine during its review process whether applications include studies or requests for waivers or deferrals.

The report was addressed to the Senate Committee on Health, Education, Labor, and Pensions and the House Committee on Energy and Commerce. The House committee will be reviewing the report in the next few days, a spokeswoman told BNA May 31.

Recently, an industry group, the Pharmaceutical Research and Manufacturers of America, urged Congress to permanently reauthorize the two pediatric laws. PhRMA said that permanently reauthorizing these acts would allow pediatric research to continue to thrive and would create more therapeutic options for children and health care providers (10 MRLR 316, 5/4/11).

More information about the report is at http://www.gao.gov/new.items/d11457.pdf.

Research Funding

House Passes Senate Bill Extending SBIR/STTR Programs for Four Months

In a down-to-the wire vote amid a sometimes-confusing series of events, the House of Representatives May 31 passed a four-month extension of the Small Business Innovation Research and Small Business Technology Innovation programs while longer-term reauthorization for the programs remains stalled in both houses of Congress.

The Small Business Temporary Extension Act of 2011 (S. 1082; Pub. L. No. 112-17) was passed by the House, 387-33. The Senate passed it May 26. President Obama signed the measure June 1.

The confusion stemmed from Senate actions concerning the legislation that resulted in announcements that the reauthorizations for the programs, which are both widely utilized by life sciences start-up companies, had been signed into law four days earlier.

Sen. Mary Landrieu (D-La.), to avoid a complete shutdown of the programs, which were both scheduled to expire May 31, introduced S. 990 May 12 to provide a one-year extension (10 MRLR 343, 5/18/11). The Senate and House passed S. 990, and Obama signed the legislation May 26, prompting the media to announce that the SBIR/STTR programs had been extended. But along the way to the House and Senate votes, S. 990 was amended to replace the SBIR/STTR language with the ''PATRIOT Sunsets Extension Act of 2011,'' which extends the Patriot Act for four years.

This same maneuver gutted an SBIR/STTR bill in the last hours of the 111th Congress when H.R. 2965, the ''SBIR/STTR Reauthorization Act of 2009,'' was passed by the House and the Senate and signed by the president, but only after the SBIR/STTR language was replaced by text repealing the ''Don't Ask, Don't Tell'' policy for gays and lesbians in the U.S. military (10 MRLR 20, 1/5/11).

After S. 990 was amended, Landrieu May 26 quickly introduced S. 1082 to extend the programs to Sept. 30. The Senate passed the bill the same day without amendments and by unanimous consent.

Reactions. House Small Business Committee Chairman Sam Graves (R-Mo.) said in a statement after the House passed S. 1082 that the SBIR/STTR programs and five other Small Business Administration programs affected by the bill ''will help spur economic growth and create jobs by designating research and development dollars to small businesses to provide government agencies new, cost-effective solutions—all at no additional cost to the government.''

Graves added, ''We have a comprehensive reauthorization bill that has already been marked up by the Science and Technology Committee and the Small Business Committee, and is ready to be voted on in the House. H.R. 1425, 'The Creating Jobs Through Small Business Innovation Act of 2011,' has widespread bipartisan support, and I hope that the House can act very soon to pass this legislation and work with the Senate towards a long-term solution that will bring more certainty to the small business research and development community.''

Biotechnology Industry Organization (BIO) President and Chief Executive Officer Jim Greenwood said in a statement, ''We are pleased that Congress understands the importance of SBIR grants and has decided to extend the program but feel a compromise on a longer-term reauthorization is critical. The ability of the SBIR program to provide critical funding for medical research projects will remain hampered unless the SBIR program is updated to address the current realities facing small, innovative American companies.''

The four-month extension of the programs as they currently exist means the set-aside and grant amounts will remain at 2008 levels and that projects from companies majority-owned by venture capitalists are still prohibited from participating in the programs, at least until October. H.R. 1425, which has been referred to the full House, increases the set-aside for participating federal agencies to 3.5 percent from 2.5 percent, while the Senate bill, S. 493, keeps it at 2.5 percent. H.R. 1425 would allow the National Institutes of Health and the National Science Foundation to give up to 45 percent of their SBIR funds to companies that are majority-owned by more than one venture capitalist, hedge fund, or private equity fund, while S. 493 sets a cap of 25 percent for small companies majority-owned by multiple venture capitalists.

Both the House and the Senate bills have been facing opposition from various groups. Some universities want to keep the set-aside at 2.5 percent, fearing that the increase to 3.5 percent will draw away research money that is available to them. The Small Business Biotechnology Coalition urges that the House bill be amended substantially to eliminate the VC provisions. Dan Backer, SBBC advocacy director, told BNA that ''with nearly half of all NIH SBIR/STTR funds going to deep-pocketed companies owned by large institutions, we'd rather have the bill as it is killed.''

The four-month extension marks the 11th short-term continuation for the SBIR/STTR programs since 2008.

BY JOHN T. AQUINO

Nanotechnology

FDA Releases Draft Guidance Document On Nanotechnology in Regulated Products

ATLANTA—The Food and Drug Administration released draft guidance June 9 outlining its view on whether regulated products contain nanomaterials, materials made up of particles that are at least one billionth of a meter in size, or involve the application of nanotechnology, the agency announced.

FDA said it released the draft guidance, ''Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology,'' to give regulated industries greater certainty about the use of nanotechnology, the science of manipulating materials on an atomic or molecular scale, which has a broad range of applications, including improving the bioavailability of drugs, in cosmetics, and in food packaging.

The guidance is intended for manufacturers, suppliers, importers, and other stakeholders involved in nanotechnology, FDA said in the draft guidance.

In the guidance, FDA named certain characteristics, such as the size of nanomaterials and their exhibited properties, that the agency may consider when trying to identify applications of nanotechnology in regulated products.

FDA said that for products subject to premarket review, it will apply the points contained in the draft guidance after it is finalized to better understand the properties and behavior of engineered nanomaterials.

For products not subject to premarket review, FDA will urge manufacturers to consult with the agency early in a product's development so that questions about a product's regulatory status, safety, effectiveness, or the public health effect can be adequately addressed, the agency said.

'Not a Regulatory Definition.' FDA Commissioner Margaret A. Hamburg said the draft guidance is not ''a regulatory definition of nanotechnology. However, as a first step, we want to narrow the discussion to these points and work with industry to determine if this focus is an appropriate starting place.''

The agency said it is ''critical for FDA to understand how changes in physical, chemical, or biological properties seen in nanomaterials affect the safety, effectiveness, performance, or quality of a product that contains such materials.''

FDA also said the draft guidance does not address the regulatory status of products that contain nanomaterials or otherwise involve the application of nanotechnology, which are addressed on a case-by-case basis using FDA's review process.

The draft guidance said FDA to date has not established regulatory definitions of nanotechnology but acknowledged that the most common term refers to materials that range in size from one to 100 nanometers.

FDA said it will examine whether the engineered nanomaterial or end product exhibits properties or phenomena that can be attributed to its dimensions.

A notice about the guidance was published in the June 14 *Federal Register* (76 Fed. Reg. 34715). Comments are due Aug. 15. Written comments can be submitted to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, Md., 20852. Electronic comments can be submitted to http://www.regulations.gov.

The draft guidance is available at http://www.fda.gov/RegulatoryInformation/Guidances/ucm257698.htm.

Stem Cell Research

Study Finds Embryonic Stem Cell Study Ban Likely Would Harm Adult Stem Cell Research

In a review of the spectrum of human stem cell research studies—including embryonic, adult, and induced pluripotent (iPS) cells—researchers concluded that there are scientific benefits to studying all these cells, and banning research using one type of stem cell could harm studies of another type, according to a paper published June 10 in the journal *Cell*.

With funding from the National Science Foundation's Science of Science and Innovation Policy, the National Institutes of Health, and the Stanford Institute for Stem Cell Biology and Regenerative Medicine, researchers from the University of Michigan, Stanford, and the

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Mayo Clinic examined whether an increasing number of studies with a certain type of adult stem cell has changed the overall course of research in the field.

In their paper, ''Democracy Derived? New Trajectories in Pluripotent Stem Cell Research,'' the researchers analyzed more than 2,000 scientific papers from 1998 to 2010 and found adult stem cells are not replacing human embryonic stems cells in the laboratory. Instead, they concluded, the two cell types have proven to be complementary. They further wrote that any disruption of federal funding would hurt stem cell research overall.

''The incentives to use both types of cell in comparative studies are high,'' Jason Owen-Smith, a sociologist at the University of Michigan and one of the two corresponding authors, said in a June 10 statement.

Julia Lane, program director for the NSF Science of Science and Innovation Policy, said in a statement the *Cell* paper is an important study because it systematically examines the co-authorship networks of stem cell research articles and uses those to understand the interactions between two complementary areas.

''It is particularly interesting because it uses new analytical techniques to advance our understanding of how the implementation of policy in one area can affect scientific research in another area,'' Lane said.

Increasing Use of Combination of Cells. In looking at stem cell papers over the 12-year period, the study authors found that the proportion of papers using human adult and human embryonic stem cells together is growing faster than those using adult stem cells alone. For example, in 2008, 15 papers—or 5.1 percent of all papers—examined in the study reported using adult stem cells, and three of those papers combined the use of human adult and human embryonic stem cells. By 2010, 161 of 574 papers—28 percent of all papers—reported on studies of both cell technologies. Out of those 161 papers, 62.1 percent paired adult and embryonic cell lines.

Owen-Smith maintained that because use of the two cell types has become so intertwined, any federal policy that would deny funding for embryonic stem cell research ''would derail work with a nascent and exciting technology.''

Christopher Scott, a Stanford bioethicist and the other corresponding author on the paper, said in a statement that a ban on federal funding for human embryonic stem cell research would have a serious negative effect on adult stem cell research.

''We may never be able to choose between iPS and ES cell research because we don't know which type of cell will be best for eventual therapies,'' Scott said.

Lane echoed Scott's thoughts.

''The whole point with science policy is to have a more scientific basis to understand the impacts of policy decisions on science if and when those decisions are made,'' she said.

In 2007, scientists in Wisconsin and Japan published a landmark paper reporting that they were able to reprogram adult skin cells back to pluripotency (6 MRLR 631, 12/5/07), which are known as iPS cells. Opponents of embryonic stem cell research argued that this discovery renders embryonic stem cell research unnecessary, offering a way to sidestep any ethical and moral dilemmas. Those in favor of funding embryonic stem cell research countered that there is too much still unknown about iPS cells and that embryonic stem cell research remains the gold standard.

Owen-Smith noted that iPS cell research is still in its infancy.

''As a result, induced pluripotent stem cells do not offer an easy solution to the difficult ethical questions surrounding embryonic stem cell research,'' he said.

BY JEANNIE BAUMANN

*The **Cell** paper is available by subscription or purchase at http://www.sciencedirect.com/science/article/pii/S0092867411005939.*

Reporting and Disclosure

FDA Issues Guidance Document That Extends Study Safety Reporting Rule Compliance Date

The Food and Drug Administration June 6 announced new guidance on enforcement of safety reporting requirements for investigational new drug applications and bioavailability/bioequivalence studies.

FDA said it intends to ''grant a six-month period of enforcement discretion,'' extending the deadline for compliance with a reporting rule until Sept. 28. The guidance was published in the June 7 *Federal Register* (76 Fed. Reg. 32863).

The guidance, which goes into effect immediately, is intended to give stakeholders time to institute significant internal process changes so they can meet the requirements of FDA's final rule, ''Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans'' (75 Fed. Reg. 59935). Published in September 2010, the final rule amended the investigational new drug safety reporting requirements under 21 C.F.R. Part 312 and added safety reporting requirements for anyone conducting bioavailability and bioequivalence studies under 21 C.F.R. Part 320. The original compliance deadline for the final rule's reporting requirements was March 28 (9 MRLR 612, 10/6/10)(4 LSLR 938, 10/8/10).

FDA said that until Sept. 28, the agency plans to take no enforcement action under the final rule as long as sponsors and investigators comply with reporting requirements under 21 C.F.R. §§ 312.32, 312.64, and 320.31 that were in effect prior to March 28.

Written requests for single copies of the guidance should be sent to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Building 51, Room 2201, Silver Spring, Md. 20993-0002; or the Office of Communication, Outreach, and Development (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, Md. 20852-1448. Anyone interested in receiving a single copy of the guidance should send a self-addressed adhesive label to assist FDA in processing requests.

Electronic comments on the guidance should be sent to http://www.regulations.gov. Written comments should be sent to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, Md. 20852.

The guidance document is available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM257976.pdf.

Diagnostic Tests

Draft Guidance Changes Research-Only Definition, Sets Noncompliance Penalty

A draft guidance issued June 1 by the Food and Drug Administration would expand the definition of ''research use only'' diagnostic devices, and hold manufacturers responsible for noncompliance by clinical laboratory customers.

The draft guidance document is intended to clarify the types of in vitro diagnostic (IVD) products that are properly labeled ''for research use only'' (RUO) or for ''investigational use only'' (IUO).

According to FDA, RUO and IUO IVD products are distinctive in that they are devices that may themselves be used in research or investigations on human samples that eventually may lead to their clearance or approval for clinical diagnostic use, and they also may be marketed for and used in the research and investigation of other FDA-regulated products.

Thus, the manufacturer of an IUO IVD product is not necessarily the sponsor of a clinical investigation that uses such an IVD product in a study. The manufacturer of such an IUO IVD product may legally distribute the product commercially without FDA premarket review, as long as the distribution is only for investigational use.

FDA said it was concerned about the increasing illegal use of RUO or IUO tests for clinical purposes.

''The marketing of unapproved and uncleared IVD products for purposes other than research or investigation (for example, for clinical diagnostic use) has led in some cases to diagnostic use of laboratory tests with unproven performance characteristics and manufacturing controls,'' FDA said in the draft guidance. ''Use of such tests for clinical diagnostic purposes may mislead healthcare providers and cause serious adverse health consequences to patients who are not aware that they are being diagnosed with research or investigational products.''

The agency announced the guidance in a *Federal Register* notice (76 Fed. Reg. 31615). Comments are due by Aug. 30.

Intended Use. Bradley Merrill Thompson, an attorney at Epstein Becker & Green in Washington, told BNA that FDA enforcement directed at firms that overstep the RUO is all about intended use.

Thompson said he understands why FDA decided to issue a guidance to define research-only devices. Since they do not have to be approved by the agency, or manufactured under any quality standard, some companies are using the label as a shortcut, which put patients in danger.

''Research doesn't go on forever, and FDA wanted customers to certify'' that they were actually using the diagnostic device for research, Thompson said. He noted that most of the guidance does not stray from what FDA ''has been saying for years.''

The real twist, however, is that if a manufacturer learns that its laboratory customers are using a product marked as RUO or IUO for clinical purposes, it should immediately stop selling to those customers.

If a manufacturer learns that a laboratory to which it sells its RUO-labeled IVD product is using it in clinical diagnosis, ''it should halt such sales,'' the agency said in the guidance.

According to the draft, ''the mere placement of an RUO or IUO label on an IVD product does not render the device exempt from clearance, approval, or other requirements, regardless of how it is marketed. Whether it bears an RUO or IUO label, or neither, an IVD product that is not intended for research or investigational purposes would not qualify.''

Thompson predicted that the provision calling for a halt to sales ''will be controversial. It will get a strong reaction'' from labs and manufacturers.

Thompson said FDA is responsible for enforcing many of the laws based on the definition of intended use, but said the guidance was a change from its previous practice of determining intended use based on the manufacturer's conduct, rather than how a customer uses a product.

''The mantra has always been that off-label use isn't illegal, only promotion. This goes a step further,'' Thompson said, and has implications for other areas of off-label use.

Thompson told BNA he sees the new requirement as a burden on the manufacturers that most likely do not have the systems in place to enforce the ''sale halt'' provision.

''It's an integrity of process issue,'' he said. ''Salesmen will be asked to tattle on the lab customers,'' which they would not do to avoid losing a commission, Thompson said. Instead, ''labs and sales representatives will simply stop talking about how the product is intended to be used. It would be in their best interests not to know.''

Mostly Positive. With the exception of ''that one nuance,'' Thompson said the guidance is a positive effort by FDA.

The vague definitions about RUO products ''have been a sore spot with industry for decades,'' Thompson said. ''Companies have been trying to do the right thing. Getting this kind of clarity helps companies and levels the playing field.''

Thompson said the draft guidance holds ''a lot of good news for companies doing the right thing.''

As for potential enforcement, Thompson said federal prosecutors already are adept at enforcing intended use violations, so potential prosecution of manufacturers who knowingly sell RUO to a lab for clinical use would not be a burden.

''FDA rarely has to go after everyone,'' Thompson said. One or two big-name prosecutions of egregious violators ''will scare everyone else into compliance.''

BY NATHANIEL WEIXEL

The draft guidance is at http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm253307.htm.

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Taxation

IRS Seeks Comments on PPACA Fees For Comparative Research Trust Fund

The Internal Revenue Service is seeking comments on provisions of the health care reform law that fund comparative research on the benefits of medical treatments, services, procedures, and drugs, the agency said June 8 in Notice 2011-35.

The Patient Protection and Affordable Care Act created the nonprofit Patient-Centered Outcomes Research Institute to advance comparative clinical effectiveness research that aims to help patients, clinicians, purchasers, and policymakers make informed health decisions. The institute, which is not an agency or part of the U.S. government, will be funded by a Patient-Centered Outcomes Research Trust Fund that is funded in part by fees to be paid by issuers of health insurance policies and sponsors of self-insured health plans.

The law imposes a fee on each specified health insurance policy for each policy year ending after Sept. 30, 2012.

IRS will propose regulations and issue guidance on the statutory requirements for issuers and plan sponsors that pay those fees, the notice said. The notice, which asks for comments on how the fees should be determined and paid, describes potential guidance that IRS expects to propose to implement the new fees.

Comments must be received by Sept. 6.

Seeks Comments on Several Areas. The fees for the health insurance policies are based on the ''average number of lives covered under the policy,'' according to the law. The notice requested comments on methods for an issue to use in determining the average number of lives covered under a policy.

IRS also invited comments on whether guidance should provide a safe harbor—and on the scope and operation of a safe harbor—for issuers that have to report the number of lives covered on the National Association of Insurance Commissioners Supplemental Health Care Exhibit, which collects comprehensive major medical data by company, state, and market. Any method, other than the safe harbor, would require issuers that are required to file the NAIC Supplemental Health Care Exhibit to account for differences among data reported, the notice said.

IRS also wants comments on the types of health reimbursement arrangements (HRAs) that would be excluded from the definition of ''applicable self-insured health plan'' because they provide a type of coverage that, if provided by an insurance policy, would not cause the policy to be treated as a specified health insurance policy, the notice said. The agency wants to know if there are types of HRAs that should be treated as applicable self-insured health plans.

Comments also could address how future guidance could reduce administrative burdens through a reasonable method for determining the average number of lives covered under a self-insured plan, whether guidance should offer a safe harbor to allow sponsors of self-insured plans to figure the average number of lives covered using a formula, or what formulas or factors could be used to figure the number of dependents for these plans.

The notice offered several questions for practitioners to answer in responses.

IRS Notice 2011-35 is available at http://www.irs.gov/pub/irs-drop/n-11-35.pdf.

Research Funding

CRS Releases Two Reports on Efforts To Reauthorize SBIR, STTR Programs

The Congressional Research Service (CRS) June 1 released two reports that summarize the legislative history of the Small Business Innovation Research (SBIR) and the Small Business Technology Transfer (STTR) programs and the issues that are before the 112th Congress as it attempts to pass a long-term reauthorization for them.

Biotechnology companies have used the programs extensively for start-up funding.

The two reports—''The Small Business Innovation Research Program'' and ''The Small Business Innovation Research (SBIR) Program: Reauthorization Efforts''—both were authored by Wendy H. Schacht, CRS specialist in science and technology policy.

The first describes how the programs were set up to require that every federal department with a research and development budget of $100 million or more establish and operate SBIR/STTR programs with a set percentage of the agency's applicable extramural research and development budget to be used for innovative research grants. It also provides an extensive table of the number and the dollar amounts of SBIR awards since the program was created in 1982 and alludes briefly to the reauthorization efforts.

The second publication repeats some of the same information as the first but also describes in detail the bills that were passed by the House and Senate in the 111th Congress to reauthorize the programs for a longer period of time than the series of short-term extensions that have been utilized to keep them going since 2008. In addition, the report provides a table showing the differences between those House and Senate bills and between the bills the 112th Congress is considering now (*see related item in this section*).

According to the report, the most contentious issues in the reauthorization are whether small businesses majority-owned by venture capital companies should be eligible to participate in the SBIR/STTR programs and whether to increase the set-aside percentage.

''The Small Business Innovation Research Program'' and ''The Small Business Innovation Research (SBIR) Program: Reauthorization Efforts'' are available at http://op.bna.com/hl.nsf/r?Open=jaqo-8hkr4b and http://op.bna.com/hl.nsf/r?Open=jaqo-8hkr6h, respectively.

Bioterrorism

Updated Project BioShield Report by CRS Covers Bioterrorism Issues Facing Congress

An updated report released May 27 on the past, present, and future of Project Bioshield says that issues confronting Congress are whether to continue diverting the project's acquisition funding to other purposes and how to use the Strategic National Stockpile (SNS) funds.

The Congressional Research Service report, ''Project Bioshield: Authorities, Appropriations, Acquisitions, and Issues for Congress,'' is an update of the Feb. 7 and July 7, 2010, reports (9 MRLR 455, 7/21/10). The Project BioShield Act, which was proposed by President George W. Bush to address the issue of medical countermeasures for chemical, biological, radiological, and nuclear (CBRN) terrorism agents, became law in July 2004 (Pub. L. No. 108-276). The act has three main provisions:

- relaxing regulatory requirements for some CBRN terrorism-related spending, including hiring personnel and awarding research grants;
- guaranteeing a federal government market for new CBRN medical countermeasures; and
- permitting emergency use of unapproved countermeasures.

According to the report authored by Frank Gottron, CRS specialist in science and technology, the Department of Health and Human Services (HHS) has used each of these authorities.

The report says that HHS has used expedited review authorities to approve contracts and grants related to CBRN countermeasure research and development; the authority to guarantee a government market to obligate approximately $2 billion to acquire countermeasures against anthrax, botulism, radiation, and smallpox; and the emergency use authority several times, including allowing young children with H1N1 ''swine'' influenza to receive specific antiviral drugs.

The Department of Homeland Security (DHS) Appropriations Act, 2004 (Pub. L. No. 108-90) advance appropriated $5.593 billion for fiscal year 2004 to FY 2013 for CBRN countermeasures acquisitions through Project BioShield, the report says. However, subsequent Congresses have rescinded or transferred to other accounts about 19 percent of the advance appropriation to support countermeasure advanced research and development, pandemic influenza preparedness and response, and basic research and advanced countermeasure development.

In FY 2011, the Department of Defense and Full-Year Continuing Appropriations Act transferred $415 million to the Biomedical Advanced Research and Development Authority (BARDA) for countermeasure advanced development, the report says.

According to the report, since passing the Project BioShield Act, subsequent Congresses have considered additional measures to further encourage countermeasure development: the 109th Congress passed the Pandemic and All-Hazard Preparedness Act (Pub. L. No. 109-417), which created BARDA in HHS and, among other duties, oversees all of HHS's Project BioShield activities. The Pandemic and All-Hazard Preparedness Act also modified the Project BioShield procurement process.

Some stakeholders have questioned whether these changes have sufficiently improved countermeasure development and procurement, and the Obama administration is considering implementing additional changes to the countermeasure research, development, and acquisition process, the report notes.

The report says the 112th Congress will continue to address several Project BioShield-related policy issues:

- whether to continue diverting Project BioShield acquisition funding to other purposes;
- whether to change the countermeasure development and acquisition process;
- how to replace stockpiled countermeasures as they expire;
- how to use the SNS funds; and
- whether to alter federal efforts to encourage the development of broad-spectrum countermeasures.

The report says, ''The HHS has stated its interest in using Project BioShield to acquire new broad-spectrum countermeasures. However, Project BioShield contracts to date have specifically targeted individual threat agents, a strategy commonly described as 'one bug, one drug.' Congress may decide that HHS needs further guidance or authorities to encourage the development and acquisition of new broad spectrum countermeasures.''

The report can be found at http://op.bna.com/hl.nsf/r?Open=jaqo-8hdqhh.

Spain

Science Ministry Approves Research Act To Involve Private Sector, Increase Quality

MADRID—In a move it said will facilitate the mobility of researchers between the public and private sectors starting in 2012, the Spanish government June 2 published its Science, Technology and Innovation Act.

Law 14/2011, which Parliament approved May 12, will take effect six months after its publication June 2 in the Boletín Oficial del Estado, Spain's national register.

''The new science law aims for greater private sector participation in research activities, more stable employment for young researchers and greater quality in Spanish science, through a definitive and irreversible bet on research excellence,'' the Ministry of Science and Innovation said in a statement.

The law, with its 47 articles and dozens of additional provisions, replaces the Scientific and Technological Research Act of 1986. Among other things, it creates a State Research Agency, facilitates researcher mobility, and alters the Biomedical Research Act.

''In the specific area of biomedical research, [the law] recognizes the key role played by health centers,'' the law says.

In this regard, the final eighth provision of the law, which alters Law 14/2007 on biomedical research, calls for the incorporation of research personnel into national health care centers, as well as for their mobility between Spanish and international research centers.

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''Research activities, as well as national and international mobility for research purposes, will be factored into the basis of qualifications for access, promotion and, as the case may be, the development and careers of National Health System professionals who carry out health care and/or research activities,'' the provision says.

Likewise, the law creates the Spanish Research Ethics Committee and the Spanish Bioethics Committee to serve as informational, representative, and advisory bodies to regional and national lawmakers.

With regard to private sector involvement, the law corrects what it called ''weaknesses'' that the previous scientific and technological research legal framework failed to address. By encouraging private sector patronage and sponsorships, the government hopes to correct what it considers historically deficient outside support for research, development, and innovation.

BY BRETT ALLAN KING

Law 14/2011 is available, in Spanish, at http://www.boe.es/boe/dias/2011/06/02/pdfs/BOE-A-2011-9617.pdf.

State News

Florida

Jackson Laboratory Cites Tight Budget In Withdrawing Plans to Build in State

TAMPA, Fla.—The Jackson Laboratory announced June 3 that it would not establish new operations in Florida, saying it would withdraw its request for $100 million in state start-up funding.

In a statement, officials at the independent, nonprofit biomedical research institution based in Bar Harbor, Maine, cited a ''lack of funds in Florida's severely constrained state budget.'' The reduced budget provided only limited funding for economic development activities, the statement said.

A few days earlier, Florida Gov. Rick Scott (R) signed a bill (H.B. 5303) that implemented cuts in state funding for biomedical research and separately made additional cuts through line-item vetoes of provisions in the state's fiscal year 2011-2012 appropriations bill.

In March, Jackson Laboratory announced it would partner with the University of South Florida (USF), the Sarasota Memorial Health Care System, Sarasota County, and the Gulf Coast Community Foundation to develop genetics-based treatments for heart disease, Alzheimer's, and diabetes at a new research facility in Sarasota County (10 MRLR 193, 3/16/11)(5 LSLR 250, 3/11/11).

At the time, Jackson said the proposed project, to be known as the Jackson Laboratory–Florida, would be housed in a 120,000-square-foot facility in Sarasota County and in laboratories and offices in the USF Health complex in Tampa.

Insufficient Funds. Charles E. Hewett, Jackson's executive vice president, said state economic development officials were supportive but did not have access to sufficient funds to ensure a successful launch of the proposed research institute.

''We were invited to submit a much-reduced proposal to the Florida Innovation Fund, but the amount available in that fund now, and the uncertainty of future funding, made such a venture too speculative to undertake responsibly,'' he said in a written statement.

''We respect that the state had to make difficult priority decisions in order to balance the budget this year. While we regret that we cannot pursue our project, we hold the state and its officials in the highest possible regard. . . . We understand Florida's budget situation, and we will turn our attention to other priorities.''

Lane Wright, a spokesman for Scott, told BNA that Jackson officials had made their case to senior administration officials.

''Governor Scott is only interested in helping fund projects that provide a good return on investment for taxpayers,'' Wright told BNA June 9.

Officials at USF and the Sarasota Memorial Health Care System said they have agreed to continue their discussions around developing highly advanced personalized health care.

''We appreciate all the work that Jackson, the Legislature and everyone working on this project has done,'' Sarasota Memorial Chief Executive Officer Gwen MacKenzie said in a joint statement.

''We certainly recognize that state lawmakers faced one of their most challenging budget years as they struggled to balance myriad needs. While we are sorry to lose the opportunity to partner with Jackson, we remain keenly interested in the opportunity to work with USF and develop a new plan to bring personalized medicine to our community.''

State Research Funding Cuts. H.B. 5303, signed by Scott May 31, implemented cuts in state funding for biomedical research of about $60 million in the coming 2011-12 fiscal year.

The cuts came in addition to other reductions included in some $615 million in line-item vetoes for what Scott termed ''special-interest earmarks'' before signing the state's $69.1 billion budget.

According to a summary of H.B. 5303, reductions contained in the bill—which applied state statutes to appropriations funding decisions for biomedical research contained in the state appropriations bill (S.B. 2000)—included:

- to $25 million from $50 million, the amount of revenue from the cigarette surcharge deposited in the Health Care Trust Fund to be reserved and subsequently transferred to the Biomedical Research Trust Fund within the Department of Health;
- to $5 million from $20 million, funding to the James and Esther King Biomedical Research Program;
- to $5 million from $20 million, funding to the William G. ''Bill'' Bankhead Jr. and David Coley Cancer Research Program; and
- to $5 million from $10 million, funding to the H. Lee Moffitt Cancer Center and Research Program.

The budget bill, however, provided $5 million for the Sylvester Cancer Center at the University of Miami and $5 million for the University of Florida Shands Cancer Center, according to the summary.

Vetoes Cut Other Funding. Meanwhile, Scott on May 26 signed the state's FY 2011-2012 appropriations bill after the line-item vetoes, a number of which included cuts to education construction and other funding as well as biomedical research.

Among the vetoed appropriations were:

- $2 million for the Sanford-Burnham Medical Research Institute;
- $1.2 million to the University of Miami for cancer research;
- $500,000 to the University of South Florida Medical Center for neuromusculoskeletal research;
- $500,000 for the Miami Project to Cure Paralysis;

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■ $500,000 for the Statewide Brain and Tumor Research Program at the McKnight Brain Institute at the University of Florida;

■ $286,000 for the Islet Cell Transplantation to Cure Diabetes Project; and

■ $50,000 for biomedical research in historically black colleges and universities.

Economy Cited. In his veto message, Scott cited the economy and a $4 billion revenue shortfall for his decisions.

''In these tough economic times, the people of Florida are forced to do more with less. Families and businesses are reducing their spending and working to limit the burden of debt. I promised Floridians that their state government will make these same fiscally-responsible choices,'' Scott wrote.

''With a national government that seems oblivious to the threat of burdensome debt, I will also continue to reduce the state's reliance on federal dollars. Too often these federal dollars are presented as if they were a gift without the recognition that this is money our children and grandchildren will have to repay to foreign lenders. Furthermore, I will reject federal money that is temporary or short-term but forces Florida taxpayers to cover permanent or long-term state spending.''

Scott's cuts drew sharp criticism from Democrats in the Legislature, many of whom had urged him to veto the budget. Others said lawmakers had struggled to draft a lean budget that still provided for many important projects.

''With the stroke of a pen, Gov. Scott just made a bad budget worse. The 2011 Legislature provided Gov. Scott with a skeleton-like budget. Many essential areas such as education, healthcare and infrastructure, were funded at bare bones levels and did not receive adequate funding,'' state Sen. Eleanor Sobel (D) said in a statement.

''The heavy handed and callous way in which Rick Scott vetoed so many important projects in the state budget is unsettling. Some may say the Governor cut out waste or 'turkeys' but tell that to biomedical researchers, Crohn's and cancer patients, veterans, students, children and Holocaust survivors.''

BY DREW DOUGLAS

Additional information on H.B. 5303 is available at http://www.flsenate.gov/Session/Bill/2011/5303.

Texas

Legislature Clears Bill to Let Site Accept Imports of Low-Level Radioactive Waste

HOUSTON—The Texas Legislature sent Gov. Rick Perry (R) a bill (C.S.S.B. 1504) that would allow dozens of states to ship low-level radioactive waste—much of it generated by hospitals, universities, research institutions, and government facilities—to a planned disposal facility in West Texas.

C.S.S.B. 1504, sponsored by state Sen. Kel Seliger (R) of Amarillo, was signed in the House and Senate on May 27 following a 31-0 vote in the Senate and a 91-38 vote in the House. Texas bills must be signed by the leaders of the two legislative chambers before they can be sent to the governor.

Perry must take action on the measure by June 19.

The bill sets a 50,000 total cubic feet annual limit of low-level radioactive waste that may be shipped from waste generators that are not parties to an interstate disposal compact.

Initially set up to handle low-level radioactive waste only from Texas and Vermont, the measure would allow the facility license holder, Dallas-based Waste Control Specialists, to accept waste from 36 non-party states that were not part of the original compact. However, waste from non-party states cannot exceed more than 30 percent of the disposal site's volume, and radiation levels of waste cannot exceed limits set by the Texas Commission on Environmental Quality in the facility license.

Waste Limits, Fees. Additionally, the bill requires Waste Control Specialists to limit non-party waste accepted to an average of 120,000 curies annually in the first 10 years of disposal operations, with an annual limit of not more than 220,000 curies, according to the bill.

The bill assesses an initial 10 percent surcharge for non-party waste; the surcharge will be increased to 20 percent after the fifth anniversary of the date disposal operations begin.

The Legislature further authorized Waste Control Specialists to set the fees it will charge for accepting waste from other states. The Texas Commission on Environmental Quality will have authority to set the rates for waste from Texas and Vermont.

The bill prohibits the disposal of waste of international origin.

Texas's low-level radioactive waste site outside of Andrews is licensed by the Commission on Environmental Quality and overseen by the Texas Low-Level Radioactive Waste Compact Commission.

The facility could begin accepting waste by year-end.

Commission to Study Capacity. The bill instructs the Commission on Environmental Quality to conduct an updated study on the waste facility's capacity in 2012. The commission's executive director may prohibit the license holder from accepting additional non-party waste if the study finds that the facility's capacity will be limited.

The commission further will be required to certify that waste to be disposed at the facility is authorized for disposal under the facility's license, according to the bill.

C.S.S.B. 1504 includes a House amendment requiring Waste Control Specialists to get an amendment or modification to its current operating permit to include acceptance of waste from non-party states.

In a statement issued after lawmakers passed the bill, Waste Control Specialists Chief Executive William J. Lindquist praised the Legislature for ''recognizing waste from outside the state was necessary to make the facility affordable and cost-effective for Texas operators.

''The Texas Legislature put the best interest of Texas consumers and ratepayers first by devising a way to keep disposal costs low for Texas generators while providing tens of millions of dollars annually for the state budget through a voluntary access surcharge paid by generators outside the Texas Compact states of Texas and Vermont,'' Lindquist said in May 31 statement.

Karen Haddon, executive director of the Sustainable Energy and Economic Development in Austin, said the Legislature should have reserved the waste facility for the compact states.

''We are disappointed that the legislation will allow non-party waste to come into the state,'' Haddon said. ''Over time, we still need to be looking at transportation and emergency preparedness issues, and we at least got this on the radar screen.''

BY SUSANNE PAGANO

Text of C.S.S.B. 1504 *is available at http://www.legis.state.tx.us/tlodocs/82R/billtext/pdf/SB01504F.pdf#navpanes=0.*

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Enforcement

Research Misconduct

Physician, Research Coordinator Indicted On Charges of Falsifying Clinical Trial Data

ST. LOUIS—A federal jury in Kansas June 2 indicted a doctor and a clinical research coordinator on charges of falsifying study data in a clinical drug trial they were paid to conduct, U.S. Attorney for the District of Kansas Barry Grissom announced the same day (*United States v. Sharp,* D. Kan., No. 5:11-CR-40042, *indicted* 6/2/11).

Physician Wayne Spencer and research coordinator Lisa Sharp were charged with one count of conspiracy, three counts of mail fraud, and one count of falsifying information required by the Food and Drug Administration. The crimes were alleged to have occurred from January 2010 to May 2010 in Johnson County, Kan.

According to a statement from Grissom's office, Sharp and Spencer were employed by Lee Research Institute, which Schering-Plough Corp. hired to perform clinical drug trials on a tablet developed for treating allergies. Spencer was the principal investigator for the clinical study and Sharp was the director of clinical trials for Lee Research Institute, the statement said.

Schering-Plough's study plans called for all test subjects to be 50 years of age or older and to have ragweed-induced allergy symptoms. Schering-Plough stipulated that employees of the clinical trial facility were to be excluded as test subjects, Grissom said in the statement. Yet Sharp and Spencer reported that they had found eight test subjects who qualified for the study, even though they knew that two of the subjects were unqualified for reasons including that they were institute employees and less than 50 years old. The unqualified subjects used false names to participate in the study and were asked to have office visits while the executive director was at lunch to conceal their ineligibility, the statement said.

According to Grissom, the indictment charged Sharp and Spencer with falsely stating that physical examinations had been conducted on the two unqualified subjects, and with signing false statements to FDA indicating the clinical study was being conducted in accordance with the protocol. As a result of the fraud, Schering-Plough issued checks totaling more than $30,000 to Lee Research Institute for the study, the indictment said.

The defendants face a maximum penalty of five years in federal prison and a fine up to $250,000 on the conspiracy charge, a maximum penalty of 20 years and a fine up to $250,000 on each of the mail fraud charges, and a maximum penalty of three years and a fine up to $10,000 on the charge of providing false information to FDA.

The case is being prosecuted by Assistant U.S. Attorney Tanya Treadway.

BY CHRISTOPHER BROWN

Fraud and Abuse

Alleged Kickbacks for Using Medical Devices Set Stage for FCA Suit Against Manufacturer

Blackstone Medical Inc., the maker of devices used in spinal surgeries, is not entitled to dismissal of a former employee's whistleblower suit alleging that kickbacks, including research grants, the company paid to doctors violated the False Claims Act, the U.S. Court of Appeals for the First Circuit determined June 1 (*United States ex rel. Hutcheson v. Blackstone Medical Inc.,* 1st Cir., No. 10-1505, 6/1/11).

Chief Judge Sandra L. Lynch rejected Blackstone's arguments regarding the application of the FCA when an alleged fraudulent Medicare claim is based on noncompliance with a separate statute or legal requirement—in this case, the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b.

A compliance requirement need not appear in a statute or regulation, the court held. Conditions on the payment of a claim also may come from contract terms, like those that appear on certain forms related to Medicare reimbursement, which identify the acceptance of kickbacks as a disqualifying event.

Also, the fact that Blackstone was not responsible for submitting the Medicare claims itself cannot shield the company from FCA liability. The statute imposes liability on those who *cause* a false claim to be made, the court said, not just those who actively send the bill to the government.

After addressing the scope of liability under the FCA, the court concluded that the lower court's dismissal of the complaint should be reversed because the qui tam plaintiff's complaint adequately alleged misrepresentations regarding compliance with the AKS, and because the misrepresentation could have influenced the government's decision to pay the claims.

Kickback Scheme Explained. Susan Hutcheson worked for Blackstone for two years prior to turning whistleblower. Her complaint outlined Blackstone's alleged practice of paying kickbacks to doctors in exchange for using the company's products in certain surgical procedures. According to Hutcheson, the kickbacks included ''monthly payments under sham consulting agreements; paid development projects; research grants; royalties; exorbitant and sometimes illicit entertainment expenses; high-end travel and accommodations; speaking engagements and seminars[;] and other illegal incentives.''

The alleged result of this scheme was that the doctors performed procedures on Medicare patients using Blackstone's products and submitted claims to the federally funded health care program.

She also asserted that because compliance with the AKS is a condition of receiving payment from Medicare, Blackstone ''knowingly cause[d]'' health care providers

to present ''false or fraudulent'' claims for payment within the meaning of 31 U.S.C. § 3729(a).

The connection between the AKS and Medicare, Hutcheson explained, comes from both the provider agreement doctors and hospitals must sign in order to be eligible for reimbursement, as well as the hospital cost report applicable only to hospitals.

The first document specifically conditions payment on compliance with the AKS, while the second bars payment for services ''provided or procured through the payment directly or indirectly of a kickback.''

The case was on appeal from the U.S. District Court for the District of Massachusetts, which had dismissed Hutcheson's claims, holding that, with regard to the hospitals, the conditions were impermissibly ''hidden'' in the Medicare forms, as opposed to expressly stated in a statute or regulation. As for the doctors, the trial court found that their claims were not ''materially'' false because there was no allegation that the kickbacks, or the use of Blackstone's devices, resulted in ''medically unnecessary surgeries.''

Contracts Spelled Out AKS Requirement. Focusing primarily on the allegedly false claims made by the hospitals, the First Circuit broke Hutcheson's appeal down into two legal issues: ''First, the parties dispute whether a claim may be false or fraudulent for failure to meet an implied legal condition of payment that is found in a source other than a statute or regulation. Second, the parties dispute whether representations made by a submitting entity with respect to its own legal compliance may encompass a legal precondition of payment applicable to non-submitting parties.''

As for the first issue, the district court found, and Blackstone agreed, that because both Medicare forms spoke directly to the person submitting the claim—the doctor—AKS compliance was an implied condition of payment with regard to the hospitals.

The district court held that the condition must be laid out in a statute or regulation in order to render the hospital claims false or fraudulent.

The First Circuit disagreed. Acknowledging that both the Second and Ninth circuits reached the same conclusion as the district court, it sided with the Tenth and District of Columbia circuits in holding that failing to comply with conditions spelled out in the underlying contract can give rise to an impliedly false claim under the FCA.

Nothing in the statute's language supports a contrary conclusion, the court said, and Blackstone's concerns over the ''federalization'' of otherwise private claims were unavailing, it concluded. The FCA's requirements that a defendant act knowingly and that the claim's defects be material confine the statute's scope, it said.

FCA Reaches Non-Submitting Entities. The second issue boils down to the text of the statute, the court said.

''The district court appeared to employ the concept of certification such that a claim can be false or fraudulent only if the submitting entity knew or should have known of the underlying falsehood or fraudulence,'' the court said.

Because no allegations were made that the hospitals received any kickbacks, or that they knew or should have known about the payments, the district court dismissed the claims.

But this approach does not follow the language of the statute, the First Circuit said.

''When the defendant in an FCA action is a non-submitting entity, the question is whether that entity knowingly caused the submission of either a false or fraudulent claim or false records or statements to get such a claim paid,'' the court held.

''The statute makes no distinction between how non-submitting and submitting entities may render the underlying claim or statements false or fraudulent,'' it explained.

Not even Blackstone's warnings that the court's reading of the statute could potentially extend liability further down the supply chain than Congress could have intended was able to sway the court.

''[W]e cannot rewrite statutes,'' it said, adding that Blackstone's concerns were ''overblown.''

False or Fraudulent Claim. After rejecting both of Blackstone's arguments for narrowing the scope of the statute, the court moved on to the question ''whether Hutcheson's complaint identified a materially false or fraudulent claim.'' It did, the court concluded.

The falsity of the claims hinged on whether the provider agreement and hospital cost reports made clear that compliance with the AKS was a precondition of Medicare reimbursement, the court said.

The language of those two documents was ''sufficiently clear'' and ''more than specific enough'' to establish that both the hospitals (unwittingly) and the doctors falsely represented that the underlying transactions—the surgical procedures performed using Blackstone's equipment—did not involve kickbacks barred by the AKS, the court held.

Further, the court found that the claims were materially false as well because, it said, it could not rule out the possibility that the government would have rejected the claims had it known about the kickbacks.

Additionally, the argument put forth by the district court and Blackstone that the doctor's claims were not material because the procedures would have been performed independent of whether the kickbacks occurred was irrelevant given the clear language in the provider agreement demanding compliance with the AKS, the court held.

Judges Kermit V. Lipez and Jeffrey R. Howard joined the opinion.

Jennifer M. Verkamp, Morgan Verkamp, Cincinnati, represented Hutcheson. Charles W. Scarborough, Department of Justice, represented the United States, which did not intervene in the suit but supported Hutcheson as amicus curiae. Catherine E. Stetson, Hogan Lovells US LLP, Washington, represented Blackstone.

Full text of the opinion is available at http://pub.bna.com/lw/101505.pdf.

FDA

Agency Drug Regulators Designate Office of Compliance as 'Super Office'

The Office of Compliance in the Center for Drug Evaluation and Research (CDER/OC) has been designated a ''super office'' within the Food and Drug Administration, according to a letter from CDER Director Janet Woodcock released June 6.

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The new designation is in keeping with ''CDER/OC's expanding role, size, and importance'' in helping fulfill FDA's mandate of ''ensuring the safety, quality, and integrity of drugs for the American people.''

Noting that the drug industry FDA regulates now is a global enterprise, Woodcock said in the May 26 letter to staff that the agency's mission ''has become an increasingly complex challenge'' that has prompted the change in CDER/OC's status within the organization. Certain offices now will be subsumed in CDER's Office of Compliance in a reorganization designed to enable CDER/OC to ''align its scientific, technical, and legal capabilities with closely related program areas, leveraging . . . resources and maximizing its ability to achieve its public health mission.''

The Office of Compliance's mandate is broad, including being responsible for ensuring that drug companies comply with good manufacturing practices and proper clinical practice; ensure protection of human research subjects; report on adverse events and drug quality; establish risk evaluation and mitigation strategies (REMS) when necessary; establish requirements for drug labeling, drug approvals, and drug importation; and ensure the integrity of the supply chain.

According to the letter, CDER/OC also will now have ''three office-wide functions established in its Immediate Office, with counterparts in all sub-Offices: risk science, intelligence, and prioritization; policy and communication; and organizational strategy (strategic planning, organizational development, and [quality management systems]).''

The name of the new super office will not change and will contain four new offices. Although three of the new offices are similar to existing divisions, one office, the new Office of Drug Security, Integrity and Recalls (ODSIR), will focus on ''the challenges of globalization and an increasingly complex drug supply chain.'' ODSIR staff will deal with issues such as supply chain security, counterfeit and diverted drugs, economically motivated adulteration, import operations, and drug recalls.

Deborah Autor will serve as acting director of the new super office, after having led the Office of Compliance for the past five years.

More information about the new structure at FDA is available at http://op.bna.com/hl.nsf/r?Open=bbrk-8hltkq.

Contracts

OIG Audit Finds NIH Contract to Construct Facility Funded Appropriately Under Statute

The Health and Human Services Office of Inspector General found the National Institutes of Health complied with all the necessary statutes when it funded a four-year, initially $3 million contract—that grew to nearly $60 million—to construct an integrated research center at an Army medical command center in Maryland.

The audit, ''Appropriations Funding for National Institutes of Health Office of Research Facilities Development and Operations Contract HHSN292-2004-00002C With Jacobs Facilities Inc.'' (A-03-10-03103), is part of a larger effort by an internal review group at HHS called the ''Tiger Team'' to review program, contract, and financial personnel. For this audit, the Tiger Team looked at whether the NIH Office of Research Facilities Development and Operations (ORF) appropriately funded the contract.

According to the OIG report, ORF awarded a $2.8 million contract to Jacobs Facilities Inc., a company based in Arlington, Va., that describes itself as a ''professional technical'' organization providing scientific and specialty consulting, engineering and construction, and operations and maintenance. Under the four-year contract, Jacobs provided management support services for the design and construction of the National Institute of Allergy and Infectious Diseases Integrated Research Facility at Fort Detrick in Frederick, Md. ORF issued 25 contract modifications for additional work that increased the contract to $59.6 million.

For its review, OIG reviewed appropriations and acquisition laws and regulations and contract requirements; reviewed the Tiger Team report; reviewed contract file documentation, including the statement of work, to determine the nature of the products or services to be provided; and analyzed selected funding documents and payment vouchers to determine what appropriations were obligated, recorded, and expended.

''ORF funded the Contract in compliance with the purpose, time, and amount requirements specified in appropriations statutes. ORF had a bona fide need for the services and appropriately funded the Contract with no-year appropriations and annual appropriations from fiscal years 2004 through 2009,'' OIG concluded.

Tiger Team. The Jacobs contract was one of 21 NIH contracts reviewed by the Tiger Team. From November 2008 to February 2009, the Tiger Team assessed 176 HHS contracts, including 21 NIH contracts. For 17 of the 21 contracts, the Tiger Team identified instances in which contract funding was not consistent with the current HHS Acquisition Regulation or appropriations laws. HHS periodically has rolled out the results of these Tiger Team audits, including three reports in April (10 MRLR 322, 5/4/11) and one in June 2010 (9 MRLR 387, 6/16/10).

The HHS OIG report is available at http://oig.hhs.gov/oas/reports/region3/31003103.pdf.

Contracts

NIH Properly Paid $100 Million to Build, Operate Biocontainment Lab in Montana

The Health and Human Services Office of Inspector General found the National Institutes of Health properly awarded a seven-year, $100 million contract to build and operate a bio-containment facility and related equipment in Montana, according to an audit released June 8.

The report, ''Appropriations Funding for National Institutes of Health Office of Research Facilities Development and Operations Contract C2000326 With Higgins Development Partners, LLC'' (A-03-10-03105), is part of a larger effort by an internal group at HHS called the ''Tiger Team'' to review the program, contract, and financial personnel for 176 contracts. For this report,

OIG examined whether the NIH Office of Research Facilities Development and Operations (ORF) complied with appropriations statutes when acquiring supplies and services with appropriated funds, specifically the purpose, time, and amount requirements in the statutes.

ORF initially awarded a three-year, $2.2 million contract on April 25, 2002, to Higgins Development Partners LLC, which is based in Chicago. NIH hired Higgins for services including the planning, design, construction, and commissioning of a bio-containment facility and equipment at the Rocky Mountain Laboratories in Hamilton, Mont. After the initial contract, the OIG report said, ORF issued 35 subsequent contract modifications for additional work. That extended the contract to a seven-year period that ended June 30, 2009, and increased the total cost to $106.4 million. OIG said the contract was scheduled to remain open until July 31, 2010, to pay late invoices and process any additional changes.

To conduct the audit, OIG:

- reviewed appropriations and acquisition laws and regulations and contract requirements;
- reviewed the Tiger Team report;
- reviewed contract file documentation, including the statement of work, to determine the nature of the products or services to be provided; and
- analyzed selected funding documents and payment vouchers.

''ORF funded the Contract in compliance with the purpose, time, and amount requirements specified in appropriations statutes,'' the OIG report said. ''ORF had a bona fide need for the services and materials and appropriately funded the Contract with no-year appropriations and annual appropriations from fiscal years 2002 through 2009.''

Tiger Team. The Higgins contract was one of 21 NIH contracts the Tiger Team reviewed from November 2008 to February 2009. For 17 of the contracts, the Tiger Team identified instances in which contract funding was not consistent with HHS Acquisition Regulation or appropriations laws. HHS periodically has rolled out the results of these Tiger Team audits, including three reports in April of this year (10 MRLR 322, 5/4/11) and one in June 2010 (9 MRLR 387, 6/16/10)(*see related item in this section*).

The OIG report ''Appropriations Funding For National Institutes Of Health Office Of Research Facilities Development And Operations Contract C2000326 With Higgins Development Partners, LLC'' (A-03-10-03105), is available at http://go.usa.gov/DeG.

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RECENT ADMINISTRATIVE ACTIONS

The following chart tracks recent federal government administrative actions and warnings directed toward medical research investigators and institutions. Agencies covered in this issue include the Department of Health and Human Services Office for Human Research Protections (OHRP) and Office of Research Integrity (ORI).

DATE	ADMIN. OFFICE	RECIPIENT	RESEARCH STUDIES	ALLEGED INFRACTIONS	ACTIONS OR PENALTIES
June 9	HHS-ORI	*Postdoctoral Fellow (former):* Philippe Bois, Ph.D., St. Jude Children's Research Hospital, Memphis, Tenn.	Two published studies funded by the National Institutes of Health for which Bois was principal author: ''FOXO1a acts as a selective tumor suppressor in alveolar rhabdomyosarcoma,'' in the September 2005 *Journal of Cell Biology* (JCB 2005); and ''Structural dynamics of [alpha]-actinin-vinculin interactions,'' in the July 2005 *Molecular Cell Biology* (MCB 2005)	Knowingly and intentionally submitted false report in JCB 2005 paper by selecting specific FOXO1a immunoblot to show desired result; falsified data presented in Figure 4B of MCB 2005 by falsely labeling lane one to represent papain-only digestion, falsely labeling lane five to represent papain digestion of [alpha]VBS peptide, and inserting band in lane three to represent [alpha]VBS peptide.	Bois requested hearing before HHS administrative law judge to dispute findings; the judge found that Bois departed significantly from ''accepted practices of the relevant research community'' when he published articles that did not completely and accurately represent his research findings and had not raised genuine dispute over facts or law material to findings of research misconduct, dismissing hearing request (*Office of Research Integrity v. Bois,* Departmental Appeals Bd., Civil Remedies Div., Dec. No. CR2366, 5/16/11; http://www.hhs.gov/dab/decisions/civildecisions/cr2366a.pdf). For three years beginning May 26, Bois is debarred from eligibility for any contracting or subcontracting with any U.S. government agency and from eligibility for, or involvement in, government nonprocurement programs; and Bois is prohibited from serving in any advisory capacity to the U.S. Public Health Service, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant (http://www.gpo.gov/fdsys/pkg/FR-2011-06-09/html/2011-14273.htm).

DATE	ADMIN. OFFICE	RECIPIENT	RESEARCH STUDIES	ALLEGED INFRACTIONS	ACTIONS OR PENALTIES
May 23	HHS-OHRP	*Administrative Official:* Daniel M. Dorsa, Ph.D., Oregon Health & Science University, Portland, Ore. *Principal Investigators:* Erica Mitchell, M.D., and Timothy Liem, M.D.	Teaching Vascular Surgery Skill: Reinforcing the Practice, A Randomized, Controlled Trial (Mitchell); Perioperative Venous Thromboembolism (VTE) in Patients with a Prior History of Deep Vein Thrombosis (DVT) (Liem) (under Federalwide Assurance FWA-161)	*Mitchell study:* Study started in July 2008 but review and approval by institutional review board did not occur until October 2008; failure to obtain legally effective informed consent of subjects enrolled between July 2008 and Oct. 31, 2008, or IRB waiver of consent; and failure to report previous two serious noncompliance findings to OHRP. *Liem study:* Conducting study without IRB review and approval.	OHRP found determination about starting Mitchell study without IRB review and approval adequately addressed by OHSU corrective actions, including provision of IRB compliance and regulatory education to Mitchell and Liem and hiring of research nurse coordinator to assist those interested in conducting human subjects research and to conduct biweekly meetings with division staff to inquire about research interests and planned activities. OHRP found Liem study was reviewed and approved by OHSU IRB before research began, so allegations of noncompliance unproven. By June 13, OHSU required to provide corrective action plan to ensure that 1) no investigators involve human beings as subjects in research covered by regulations unless investigators have obtained legally effective informed consent of subjects or subject's legally authorized representative or IRB has waived consent requirements to obtain informed consent; and 2) prompt reporting to OHRP of any unanticipated risks to subjects or others, serious or continuing noncompliance with regulations or IRB determinations, and any suspension or termination of IRB approval (http://www.hhs.gov/ohrp/detrm_letrs/YR11/may11c.pdf).

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Focus on Compliance

Conflict of Interest

HHS Deputy Inspector General Says Institutional Conflicts Need Addressing

AUSTIN, Texas—Biomedical research institutions need conflict-of-interest policies for their entire organizations, not just for individuals, a deputy inspector general at the Department of Health and Human Services told attendees at the Health Care Compliance Association's Research Compliance Conference June 13.

Speaking at a general session of the conference held in Austin, Texas, Lewis Morris, who also serves as chief counsel for the HHS Office of Inspector General, said institutional conflicts do exist and federal regulations should be adopted to address such conflicts. But until such regulations are put in place, he added, research institutions must take the lead in addressing conflicts.

In particular, he said, financial decisionmaking needs to be separated from research, and institutions ''must make the case that effectively managing these conflicts is necessary to maintain the public trust.''

''In this time of deficits, . . . the scrutiny we are going to be under . . . is only going to increase,'' Lewis said. He emphasized that individuals are not good at detecting their own conflicts: Most people think they are not influenced by gifts and other benefits, but in practice, human beings have a ''natural impulse to reciprocate'' when someone else does them a favor.

Because conflicts in medical research can both waste money—taxpayer dollars in the case of research sponsored by federal agencies—and potentially harm the public, both federal agencies and institutions need to do a better job, Lewis said.

OIG Studies. The OIG has done three studies on conflicts issues in medical research. The first looked at conflicts reports provided to the National Institutes of Health and determined that 89 percent of those reports lacked detailed information about the nature of the conflict and the manner in which it was addressed (7 MRLR 64, 2/6/08). OIG recommended that NIH increase its oversight in this area and require institutions to provide more details.

In a second study, OIG looked at whether NIH's reliance on institutions to provide conflict information was well-placed (8 MRLR 800, 12/2/09). It determined that 90 percent of institutions surveyed relied solely on the researcher's discretion in determining conflicts of interest. Fifty percent of them did not require showing of any financial data related to a conflict, and most that asked for financial reports did not verify them.

Following OIG's recommendations, NIH has published a notice of proposed rulemaking in this area that includes a new definition of significant financial interest and clarifies that subgrantees are considered part of grantee institutions for this purpose.

In a third study, OIG looked at whether institutions had policies on conflicts of interest, even though they are not required to do so (10 MRLR 54, 1/19/11). Of 156 institutions that responded to a survey, fewer than half had written policies, and only 21 of those addressed financial conflicts. But of those 21, Lewis said, 18 had found such conflicts.

While the Institute of Medicine, part of the nonprofit National Academies, has recommended extending federal regulations on conflicts to include institutions, and a committee of the American Health Lawyers Association is preparing a report on best practices for hospitals that includes effective management of conflicts and separating the promotion of an industry sponsor from the promotion of science, NIH has so far declined to propose rules on institutional conflicts.

While OIG applauds the efforts by participating institutions to come up with their own policies, it would like to see a merger of different best practices into one set of guidelines. If institutions do it on their own, Lewis said, they may ''undercut the need for a federal regulation.'' If they don't, Congress is likely to get involved and require regulations. ''If you want to avoid another 'unfunded mandate,' . . . do it yourself,'' he said.

Research Misconduct. In a breakout session on research misconduct conducted by a senior counsel from the HHS Office of Research Integrity (ORI) and the research compliance director for the University of Pennsylvania's Pearlman School of Medicine, the speakers emphasized the need for written policies on research misconduct and the importance of being very organized in compiling and filing data.

Under the detailed federal regulations that took effect in June 2005 (4 MRLR 391, 5/18/05), set out at 42 C.F.R Part 93, institutions have a duty to protect Public Health Service funds from misuse as well as to protect the public health and safety, Senior HHS Attorney Jo An Rochez told the audience. Research misconduct includes things such as fabrication, falsification, or plagiarism of data, but it does not include ''honest errors or differences of opinion.''

When ORI is dealing with allegations of research misconduct, it must prove that the person in question ''intentionally, knowingly, or recklessly'' committed the misconduct, she added.

Debbi Gilad of the University of Pennsylvania gave detailed advice on how research integrity officers should deal with a complaint of misconduct within an institution. She emphasized that good faith is always important in these complaints, and issues unrelated to the research are almost always present as well. ''There's a whole story'' behind the allegation and it can include problems in people's personal lives as well as the interpersonal relations in the lab.

The research integrity officer has a duty to every person in the process: the complainant, who should never be identified by the officer even when ''everyone knows'' who it is; the respondent who has been ac-

cused; witnesses; the members of inquiry committees; and the sponsor. It is critical that the research integrity officer ensure the integrity of the process, she said.

Sequester Records. All lab records, including computers, should be sequestered when a respondent is notified that a credible complaint has been made, Gilad said. This prevents tampering with the evidence and also keeps the respondent from being accused of other misconduct. Rochez pointed out that institutions must have policies making it clear that the data are owned by the institution, not the scientist, because scientists who own the data may refuse to allow them to be reviewed.

However, in most cases the research itself is not stopped during the inquiry period, though in some cases a new principal investigator may be put in charge of the research, the speakers said.

If an initial inquiry leads to an institutional investigation, the hospital or university is required to notify ORI. Once the institution has made a finding of misconduct, ORI begins its own process of administrative action.

There are situations when an institution has found misconduct but ORI decides not to pursue the allegation further. In one such situation, Rochez said, the researcher sued the institution, alleging that the lack of an action by ORI meant the institution acted with malice.

The U.S. District Court for the Southern District of New York disagreed. ''ORI's determination does not vindicate [the respondent],'' the court said in *Chao v. Mount Sinai Hospital* (S.D.N.Y., No. 1:10-cv-02869, 12/17/10) (10 MRLR 23, 1/5/11).

BY NANCY J. MOORE

Conference materials are available at http://www.hcca-research-conference.org/pastconf/2011/.

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BNA Insights

The Supreme Court's Decision in *Stanford v. Roche*: Important Implications for Research Institutions

BY DAVID W. BURGETT AND J. TREVOR CLOAK

On June 6, the Supreme Court issued its much-anticipated ruling in *Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems, Inc.*[1] By a 7–2 majority, the court held that the Bayh-Dole Act, 35 U.S.C. §§ 200-212, does not automatically vest title in a federally funded invention to a federal contractor or grantee. The implications of the decision are important for all research institutions that receive federal funds, either directly or indirectly as a sub-awardee.

Background

In 1988, Dr. Mark Holodniy joined Stanford University's Department of Infectious Diseases as a research fellow. In so doing, he signed a copyright and patent agreement (CPA) whereby he '' 'agree[d] to assign' to Stanford his 'right, title and interest in' inventions resulting from his employment at the University.''[2] To assist Dr. Holodniy in his research on quantifying HIV using polymerase chain reaction (PCR), Dr. Holodniy's supervisor arranged for Dr. Holodniy to work at Cetus Corp., a Stanford collaborator that developed PCR.[3] At Cetus's request, Dr. Holodniy signed a visitor's confidentiality agreement (VCA) that stated that he '' 'will assign and do[es] hereby assign' to Cetus his 'right, title and interest in each of the ideas, inventions and improvements' made 'as a consequence of [his] access' to Cetus.''[4] While at Cetus, Dr. Holodniy developed a PCR-based procedure that was capable of quantifying the amount of HIV in a patient's blood. He later returned to Stanford to test it.[5]

Stanford eventually obtained written assignments of rights from Dr. Holodniy and other Stanford employees, and filed patent applications covering Dr. Holodniy's procedure.[6] Because ''[s]ome of Stanford's research related to the HIV measurement technique was funded by the National Institutes of Health (NIH),''[7] Stanford ultimately elected to retain title to the invention pursuant to the Bayh-Dole Act, which allows a nonprofit organization to ''elect to retain title'' to an invention ''conceived or first actually reduced to practice in the performance of work under a [federal government] funding agreement'' so long as certain prior requirements are met.[8] Three patents subsequently were issued on applications, one each in 1999, 2003, and 2006.[9]

In the meantime, Roche Molecular Systems purchased Cetus's PCR business, including all rights under the VCA,[10] and began commercializing and selling HIV test kits that embody Dr. Holodniy's procedure. Accordingly, in 2005, Stanford filed suit in district court alleging that Roche's sale of its HIV kits infringed Stanford's patents.[11] Roche counterclaimed, averring, *inter alia*, that it was a co-owner of the patented invention based on its purchase of Cetus's PCR business and the associated rights under the VCA.[12] In response, Stanford argued that Dr. Holodniy did not have any interest to assign to Cetus because under the Bayh-Dole Act Stanford had a ''right of second refusal'' to obtain patent rights in the claimed invention, which Stanford appropriately exercised, thereby giving it title to the invention.[13]

The district court agreed with Stanford, holding that the Bayh-Dole Act gave Stanford a ''superior right to retain title to the patents.''[14] Thus, ''[b]ecause Stanford exercised its right [under the Act] and obtained title in the patents, Holodniy had no interest to assign to Cetus [and t]he assignment provision in the VCA [wa]s therefore void.''[15] On appeal, the Federal Circuit disagreed, holding that ''the Bayh-Dole statutory scheme did not automatically void the patent rights that Cetus received from Holodniy'' because the ''primary purpose of the [Act] is to regulate relationship of small business and

[1] 563 U.S.___, No. 09-1159, 6/6/11.
[2] *Stanford v. Roche*, slip op. at 2.
[3] *Id.* at 1-2.
[4] *Id.* at 2.
[5] *Id.*
[6] *Id.*
[7] *Id.* at 4
[8] 35 U.S.C. §§ 201, 202.
[9] *Stanford v. Roche*, slip op. at 2; *see also, Stanford v. Roche*, 583 F.3d 832, 838 (Fed. Cir. 2009).
[10] *Stanford v. Roche*, slip op. at 2-3.
[11] *Id.* at 4.
[12] *Id.*
[13] *Stanford v. Roche*, 487 F. Supp. 2d 1099, 1117-1119 (N.D. Cal. 2007).
[14] *Id.* at 1119.
[15] *Id.*

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Trevor Cloak is an associate in the firm's IP group.

non-profit grantees with the Government, not between grantees and the inventors who work for them.''[16]

With the support of friends of the court briefs from the solicitor general and members of the university community, Stanford argued before the Supreme Court that the Bayh-Dole Act automatically vests patent title in a university performing federal research, thereby trumping any purported assignment of the same invention by the inventor to a third party.

In a decision delivered by Chief Justice John Roberts, the Supreme Court rejected that view and affirmed the Federal Circuit's decision, holding that the Bayh-Dole Act does not ''automatically vest[] title to federally funded inventions in federal contractors.''[17] The Court reasoned that generally, ''rights in an invention belong to the inventor.''[18] And while various federal statutes had in the past vested title to certain inventions in the United States, thereby supplanting this general rule, such express vesting language ''is notably absent from the Bayh-Dole Act.''[19] Moreover, the majority reasoned, the Act's language, which allows federal contractors ''to elect to retain title to'' any ''invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement,''[20] suggests against a vesting interpretation. Instead, the use of the word ''retain'' implies that title to a subject invention already must be owned by the federal contractor, not that title is vested automatically in that contractor.[21] Moreover, the ''of the contractor'' language suggests that a subject invention must be owned by the federal contractor at the time it elects to retain title under the Act.[22] Thus, the majority concluded, ''[t]he Bayh-Dole Act does not confer title to federally funded inventions on contractors or authorize contractors to unilaterally take title to those inventions; it simply assures contractors that they may keep title to whatever it is they already have.''[23] Such interpretation is further bolstered by the remaining provisions in the Act, as well as the ''limited scope of the Act's procedural protections.''[24]

The two dissenters, Associate Justices Stephen Breyer and Ruth Bader Ginsburg, would have returned the case to the Federal Circuit for further briefing as to (1) whether the assignments gave rise only to equitable, rather than legal, title; and (2) whether the Bayh-Dole Act requires an inventor to assign a federally-funded invention to his employer.[25] They stopped just short of stating they would have ruled for Stanford, expressing instead ''tentative'' views that the Court's interpretation of Bayh-Dole ''likely'' was wrong.

Implications of the Decision

What are the consequences of *Roche* for research institutions? For most, if not all, the long-term outlook is not dire, but there may be challenges for some during a transitional period. For the long term—that is, for inventions conceived after institutional policies and agreements have been updated (if necessary) and have taken effect—the situation should be manageable. The key is to ensure that such policies effect a present assignment of inventions conceived or reduced to practice during the term of institutional employment, and that those policies are effectively incorporated in the conditions of employment of each researcher who may help create inventions. In addition, it is good practice to require researchers to execute confirmatory documents upon request, which may be done, for example, at the time of invention disclosure.

Many institutions have long had policies of this kind, but some have made or will make changes in response to *Roche*. If a policy is changed, questions may arise as to if and when it becomes applicable to new inventions, prior inventions, and to staff whose hiring predates the policy change.

Institutional terms of employment ought to, and typically do, require employees to abide by institutional policies as they are added or amended from time to time. Such a requirement is a practical necessity because requirements inevitably evolve and it is untenable to have different staff subject to different rules and procedures depending on their respective hiring dates. Institutions can expect that their policies—if properly worded, adopted, and promulgated to staff—will apply at least for inventions made after the effective date of the policy.

Researchers might protest that such a policy change effects too fundamental a change in their rights as inventors to be imposed unilaterally. But that objection is not very persuasive because the change from ''agree to assign'' to ''hereby assign'' is only one of timing in achieving the same result. The change does not alter institutional policy regarding patent ownership; in either case, the institution already is identified as the rightful ultimate owner.

Before 2008, there may have been a risk that institutions in some states would find it difficult to protect their proprietary interest because of state court precedents refusing to enforce assignments of inventions not yet in existence. However, this risk appears to have been alleviated by the Federal Circuit in *DDB Technologies LLC v. MLB Advanced Media LP*.[26] The court held that ''[a]lthough state law governs the interpretation of contracts generally . . . , the question of whether a patent assignment clause creates an automatic assignment or merely an obligation to assign is intimately bound up with the question of standing in patent cases. We have accordingly treated it as a matter of federal law.''[27] Thus, ''[a]pplying federal law, [the court has] held that whether an assignment of patent rights in an agreement . . . is automatic, requiring no further act on the part of the assignee, or merely a promise to assign depends on the contractual language. If the contract expressly grants rights in future inventions, 'no further act [is] required once an invention [comes] into being,' and 'the transfer of title [occurs] by operation of law.' . . . Contracts that merely obligate the inventor to grant rights in the future, by contrast, 'may vest the promisee with *equitable* rights in those inventions once made,' but do not by themselves 'vest *legal* title to patents on

[16] *Stanford v. Roche*, 583 F.3d at 845 (internal citation omitted).
[17] *Stanford v. Roche*, slip op. at 1.
[18] *Id.* at 7.
[19] *Id.* at 8.
[20] *Id.* at 9-10.
[21] *Id.* at 11.
[22] *Id.* at 10.
[23] *Id.* at 11.
[24] *Id.* at 12-14.
[25] *Id.* at dissent at 8.
[26] 517 F.3d 1284 (Fed. Cir. 2008).
[27] *Id.* at 1290.

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the inventions to the promisee.' ''[28] Thus, a present assignment of future patents should be effective if worded properly. Since the Federal Circuit has nationwide jurisdiction over appeals of patent infringement cases, its decisions in this field generally ensure uniformity.

But what about inventions that predate the policy change? With proper wording of the policy, it likely also could be made to apply to prior inventions that the inventor still owns, *i.e.*, that the inventor has not already assigned to a third party, as Dr. Holodniy did. As for inventions already assigned to third parties, it is doubtful that any relief is possible. This is the same situation that occurred in *Roche* and likely would have the same outcome.

[28] *Id.* (internal citations omitted).

Institutions would be well advised to ''clean up'' their backlogs of inventions whose ownership is at risk, to the extent possible. Institutions may wish to undertake a review to identify and study any third-party research agreements that researchers have in place. This could represent a significant increase in workload for institutions that have not previously sought to review researchers' individual consulting agreements. Alternatively or concurrently, an institution may undertake a more targeted review of its portfolio of disclosed inventions. This would include specifically inquiring of the inventors whether they entered any third party agreement in connection with work that led to the invention or its actual reduction to practice. In addition, researchers should be advised not to sign agreements with third parties regarding university-related research without first showing them to university IP counsel.

Journal

LEGISLATIVE CALENDAR

Committees

House Rules, full committee met June 13 to formulate a rule for floor debate of H.R. 2112, making fiscal 2012 appropriations for agriculture, rural development, Food and Drug Administration, and related agencies.

House Science, *Research Subcommittee,* held a hearing June 2 on social, behavioral, and economic science research (*see related item in the News section*).

Report

H.R. 2112, making appropriations for Agriculture, Rural Development, Food and Drug Administration, and Related Agencies programs for the fiscal year ending Sept. 30, 2012, and for other purposes (H. Rept. 112-101), June 3.

Bills

S. 1167 (PUBLIC HEALTH), to amend the Public Health Service Act to improve the diagnosis and treatment of hereditary hemorrhagic telangiectasia, and for other purposes; JOHNSON of South Dakota and BINGAMAN; to Health, Education, Labor, and Pensions, June 9.

H.R. 2144 (GLOBAL HEALTH), to amend the Foreign Assistance Act of 1961 to codify the cooperative agreement, known as the Health Technologies Program, under which the United States Agency for International Development supports the development of technologies for global health, and for other purposes; SIRES; to the Committee on Foreign Affairs, June 3.

H.R. 2123 (PUBLIC HEALTH), to amend the Public Health Service Act to improve the diagnosis and treatment of hereditary hemorrhagic telangiectasia, and for other purposes; GALLEGLY; jointly, to Energy and Commerce and Ways and Means, June 3.

H.R. 290 (EDUCATION), expressing the sense of the House that it is imperative that the United States creates a clear vision and goal to be the world leader in innovation, science, technology, engineering, and math to ensure the continued strength, growth, and vitality of this nation; FATTAH; to Science, June 1.

Public Law

S. 1082, to provide for an additional temporary extension of programs under the Small Business Act and the Small Business Investment Act of 1958, and for other purposes; signed June 1, 2011 (Pub. L. No. 112-17) (*see related item in the News section*).

REGULATORY CALENDAR

Notices

Office of Science and Technology Policy announced the schedule and summary agenda for a partially closed meeting of the President's Council of Advisors on Science and Technology (PCAST). The meeting will be held July 15 at the Marriott Metro Center, 775 12th Street N.W., Ballroom Salon A, Washington, D.C. During the open part of the meeting, PCAST tentatively is scheduled to hear presentations on the U.S. patent system, the activities of the U.S. Chief Information Officer, and the future of the U.S. science and technology research enterprise. The meeting will include a public comment period. Additional information and the agenda, including any changes that arise, will be posted on the PCAST website at http://whitehouse.gov/ostp/pcast. (This notice was scheduled to appear in the June 15 *Federal Register*.)

Food and Drug Administration announced the availability of the draft guidance ''Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology.'' The guidance is intended to provide industry with FDA's current thinking on whether FDA-regulated products contain nanomaterials or otherwise involve the application of nanotechnology. The guidance is available at http://www.fda.gov/RegulatoryInformation/Guidances/ucm257698.htm or http://www.regulations.gov, or submit written requests for copies of the guidance to the Office of Policy, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, Md. 20993-0002. Comments are due Aug. 15. Submit comments to http://www.regulations.gov or to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, Md. 20852 (76 Fed. Reg. 34715, 6/14/11) (*see related item in the News section*).

Centers for Medicare & Medicaid Services announced it intends to sponsor a federally funded research and development center (FFRDC) to facilitate the modernization of business processes and supporting systems and their operations. This is the third of three notices that must be published over a 90-day period to advise the public of the agency's intention to sponsor an FFRDC. Comments, which are due July 5, must be mailed to the Centers for Medicare & Medicaid Services, Candice Savoy, Contracting Officer, 7500 Security Blvd., Mailstop C2-01-10, Baltimore, Md. 21244, or by e-mail to Candice.Savoy@cms.hhs.gov (76 Fed. Reg. 34713, 6/14/11).

Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, announced it has established the Advisory Council on Alzheimer's Research, Care, and Services, under the National Alzheimer's

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Project Act. Also, the notice requests nominations for 12 members to serve on the council for a term of four years. The council will meet quarterly to discuss programs that affect people with Alzheimer's disease and related dementias and their caregivers. The council will make recommendations about ways to reduce the financial impact of these conditions and improve patients' health and will provide feedback on the national plan for Alzheimer's disease. Also, on an annual basis, the council will evaluate the implementation of the recommendations through an updated national plan. Submit nominations by June 30 to Helen Lamont at helen.lamont@hhs.gov or mail to Office of the Assistant Secretary for Planning and Evaluation, Room 424E, Humphrey Bldg., Department of Health and Human Services, 200 Independence Ave., S.W., Washington, D.C. 20201 (76 Fed Reg. 34074, 6/10/11).

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FDA announced that the Office of Management and Budget approved a collection of information entitled ''Guidance for Industry on Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act'' under the Paperwork Reduction Act of 1995. The approval expires on April 30, 2014 (76 Fed Reg. 34083, 6/10/11).

FDA announced that the Office of Management and Budget approved a collection of information entitled ''Institutional Review Boards'' under the Paperwork Reduction Act of 1995. The approval expires on April 30, 2014 (76 Fed Reg. 34085, 6/10/11).

FDA said it is seeking public comment on a proposed collection of information, ''Requirements for Submission of Bioequivalence Data—21 CFR Parts 314 and 320 (OMB Control Number 0910-0630)—Extension,'' under the Paperwork Reduction Act of 1995. FDA seeks comments on the requirement for an abbreviated new drug application applicant to submit data from all bioequivalence studies the applicant conducts on a drug product formulation submitted for approval. Submit comments by Aug. 9 to http://www.regulations.gov or to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, Md., 20852 (76 Fed Reg. 34081, 6/10/11).

HHS published a notice requesting comments on the proposed information collection, ''Provide Services for the Dissemination of CER to Patients and Providers to Increase Adoption—OMB No. 0990-New-Assistant Secretary for Planning and Evaluation (ASPE),'' in accordance with the Paperwork Reduction Act of 1995. The project's purpose is to strengthen the link between evidence production and strategies for conveying the information in ways that encourage evidence-based behavior change among providers and patients. The prominent question is how best to get comparative effectiveness research information to physicians and patients in a way they understand. To get copies of the supporting statement and forms for the collection, e-mail your request, including your address, phone number, OMB number, and OS document identifier, to Sherette.funncoleman@hhs.gov, or call the reports clearance office at (202) 690-5683. Fax comments by July 11 to the OS Office of Management and Budget (OMB) Desk Officer at (202) 395-5806 (76 Fed. Reg. 33761, 6/9/11).

Nuclear Regulatory Commission announced it corrected a document about a proposed rule published in the *Federal Register* on May 20, 2011 (76 Fed. Reg. 29171) regarding medical use regulations. The Regulatory Identifier Number that appears in the heading, RIN 3150-AI28, is corrected to read RIN 3150-AI26. Also, in the background information section, NRC added information regarding the availability of the preliminary draft rule language. Subjects in the proposed rule include medical event reporting requirements for permanent implant brachytherapy, amending preceptor attestation requirements, extending grandfathering to certified individuals, revising Part 35 to allow assistant/associate radiation safety officers on a license, requiring molybdenum breakthrough tests after each elution and requiring reporting of failed molybdenum breakthrough tests, and other items. For information, contact Cindy Bladey, Chief, Rules, Announcements, and Directives Branch, Office of Administration, Nuclear Regulatory Commission, Washington, DC 20555-0001, e-mail: Cindy.Bladey@nrc.gov, telephone (301) 492-3667 (76 Fed. Reg. 33173, 6/8/11).

FDA announced that the guidance ''Enforcement of Safety Reporting Requirements for INDs and BA/BE Studies'' is available. FDA said it intends to enforce the reporting requirements in the final rule, ''Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans'' (75 Fed. Reg. 59935, 9/29/10), until Sept. 28, 2011, in response to requests to extend the March 28, 2011, date of the final rule. FDA expects all sponsors and investigators to be in compliance with the new regulations no later than Sept. 28. See the guidance at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm , or http://www.regulations.gov. Submit written requests for copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Building 51, Room 2201, Silver Spring, Md. 20993-0002; or the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Ad-

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ministration, 1401 Rockville Pike, Suite 200N, Rockville, Md. 20852-1448 (76 Fed. Reg. 32863, 6/7/11).

FDA announced it will accept and consider applications to help it work with the World Health Organization (WHO) on a collaboration involving regulatory science and the National Regulatory Authorities (NRAs) to advance global access to safe and effective vaccines and other biologicals that meet international standards. The goal is to enhance technical collaboration and cooperation among FDA, WHO, and its member states. For more information on this funding opportunity, go to http://www.grants.gov and/or http://www.fda.gov/BiologicsBloodVaccines/ScienceResearch/ucm251665.htm. The application due date is July 8, 2011, the anticipated start date is Aug. 15, 2011, and the expiration date is July 9, 2011. For information, contact Gopa Raychaudhuri, Center for Biologics and Evaluation and Research, Liaison to the World Health Organization, Food and Drug Administration, 1401 Rockville Pike (HFM-30), Suite 200N, Rockville, Md. 20852, (301) 827-6352, or gopa.raychaudhuri@fda.hhs.gov; Leslie Haynes, Foreign Regulatory Capacity Building Coordinator, International Affairs, Food and Drug Administration, 1401 Rockville Pike (HFM-30), Suite 200N, Rockville, Md. 20852, (301) 827-3114, or leslie.haynes@fda.hhs.gov; or Vieda Hubbard, Grants Management Specialist, Office of Acquisitions and Grants Services, Food and Drug Administration, 5630 Fishers Lane (HFA 500), Room 2141, Rockville, Md., 20857, (301) 827-7177, or vieda.hubbard@fda.hhs.gov (76 Fed. Reg. 32364, 6/6/11).

HHS published a notice requesting information on the ''Preliminary Plan for Retrospective Review of Existing Regulations,'' in accordance with Executive Order 13563, ''Improving Regulation and Regulatory Review.'' The purpose of the preliminary plan is to identify a preliminary list of regulations that are appropriate candidates for review over the next two years and establish an ongoing process of retrospective review of existing regulations by which HHS can determine whether any should be modified, streamlined, expanded, or repealed. Submit comments electronically by June 30 to http://www.hhs.gov/open or http://www.regulations.gov. Comments may also be mailed to Department of Health and Human Services, Office of Documents and Regulations Management, Attn: HHS-ES-2011- 002, 200 Independence Ave., S.W., Suite 639G, Washington, D.C. 20201 (76 Fed. Reg. 32330, 6/6/11).

FDA announced the availability of the draft guidance entitled ''Commercially Distributed In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only: Frequently Asked Questions.'' To get a copy of the guidance using the Internet, do a search at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. Submit written requests for single copies to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Building 66, Room 4613, Silver Spring, Md. 20993, or the Office of Communication, Outreach and Development (HFM-40), 1401 Rockville Pike, Suite 200N, Rockville, Md. 20852. Submit written or electronic comments on the guidance by Aug. 30 to http://www.regulations.gov or to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, Md. 20852 (76 Fed. Reg. 31615, 6/1/11).

Correction

FDA June 3 corrected the notice that announced the availability of ''Guidance for Clinical Investigators, Industry, and FDA Staff: Financial Disclosure by Clinical Investigators'' because the document, from the May 24 *Federal Register* (76 Fed. Reg. 30175), was published with an incorrect docket number. The document is corrected to read ''[Docket No. FDA-1999-D- 0742] (formerly Docket No. 1999D-4396).'' (76 Fed. Reg. 32367, 6/6/11).

CONFERENCES & MEETINGS

June 2011

47th DIA Annual Meeting, June 19-23, 2011, Chicago

Contact: Drug Information Association, (215) 442-6100; http://www.diahome.org/DIAHome/FlagshipMeetings/Home.aspx?meetingID=23753

OHRP Research Community Forum: Protecting Human Subjects: Blending Regulatory Requirements and Best Practices, June 21, Boston

Contact: Dana-Farber Cancer Institute, (617) 632-3029; https://oprs.dfci.harvard.edu/conference/index.asp

NACUA 2011 Annual Conference, June 26-29, 2011, San Francisco

Contact: National Association of College and University Attorneys, (202) 833-8390; http://www.nacua.org/meetings/annualconference.asp

BIO International Convention, June 27-30, 2011, Washington

Contact: Biotechnology Industry Organization, (202) 962-9200; http://convention.bio.org/

July 2011

OHRP Workshop: Developing Human Research Protections Program: Regulatory Compliance and Additional Considerations, July 7, Albuquerque, N.M.

Contact: HHS Office for Human Research Protections, (301) 577-0244 (registration), (240) 453-8207 (program content); http://www.blsmeetings.net/OHRPQualityassurance/

August 2011

IQPC 5th Biobanking Conference, Aug. 22-24, San Francisco

   ISSN 1539-1035

Contact: International Quality & Productivity Center, 800-882-8684; http://www.biobankingconference.com/

Office of Research Integrity Quest for Research Excellence 2011, Aug. 29-30, Washington

Contact: HHS Office of Research Integrity/Georgetown University, (201) 687-8425; http://regonline.com/questconference

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BNA
MEDICAL RESEARCH LAW & POLICY REPORT

Electronic Resources

VOL. 10, NO. 12 JUNE 15, 2011

THIS WEEK'S ISSUE

Listed below are the headlines and page numbers of selected articles in this issue followed by websites providing related information.

High Court's *Stanford* Ruling Places Special Demands on Research Entities, Attorneys Say (p. 403)
http://pub.bna.com/ptcj/091159Jun6.pdf

Review of Final NIH Conflict of Interest Rule Extended by OMB; No Release Date Indicated (p. 407)
http://www.reginfo.gov/public/do/eoPackageMain, http://bit.ly/INVhLf

ClinicalTrials.gov Increases Transparency; Improving Subjects' Experience May Be Next (p. 408)
http://bit.ly/kaNeGV

Coburn Decries NSF Management, Programs, Wants to Eliminate Social Science Funding (p. 410)
http://1.usa.gov/mT7gtb, http://1.usa.gov/4dwQg1, http://science.house.gov/hearing/subcommittee-research-and-science-education-hearing-social-bahavioral-and-economic-science, and http://www.aau.edu/research/societal_benefits.aspx

GAO Faults FDA Tracking Procedures for Pediatric Drug Studies in New Report (p. 416)
http://www.gao.gov/new.items/d11457.pdf

FDA Releases Draft Guidance on Nanotechnology in Regulated Products (p. 418)
http://www.fda.gov/RegulatoryInformation/Guidances/ucm257698.htm

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Index-Summary updates for Medical Research Law & Policy Report are available on a monthly basis.
http://www.bna.com/current/mrl/

INTERNET SOURCES

Listed below are the addresses of websites consulted by editors of BNA's Medical Research Law & Policy Report and websites for official government information.

Association of Academic Health Centers
http://www.aahcdc.org/

Association of American Medical Colleges
http://www.aamc.org

Association of American Universities
http://www.aau.edu/

Health Care Compliance Association
http://www.hcca-info.org

National Association of College and University Attorneys
http://www.nacua.org/

National Council of University Research Administrators
http://www.ncura.edu/

Public Responsibility in Medicine & Research
http://www.primr.org

Society of Research Administrators International
http://www.srainternational.org

BNA PRODUCTS

BNA's Health Care Daily Report
http://www.bna.com/products/health/hdln.htm

BNA's Health Care Fraud Report
http://www.bna.com/products/health/hfra.htm

BNA's Health Care Program Compliance Guide
http://www.bna.com/products/health/hccg.htm

BNA's Health Insurance Report
http://www.bna.com/products/health/hir.htm

BNA's Health IT Law & Industry Report
http://www.bna.com/products/health/hiln.htm

BNA's Health Law & Business Library
http://www.bna.com/products/health/hlbs.htm

BNA's Health Law Reporter
http://www.bna.com/products/health/hlr.htm

BNA's Life Sciences Law & Industry Report
http://www.bna.com/products/health/lsir.htm

BNA's Medical Devices Law & Industry Report
http://www.bna.com/products/health/meln.htm

BNA's Pharmaceutical Law & Industry Report
http://www.bna.com/products/health/plir.htm

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